EXHIBIT D

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE No. 2:12-MD-02327
THIS DOCUMENT RELATES TO	MDL 2327
GENERAL DEPOSITION RE: TVT	JOSEPH R. GOODWIN US DISTRICT JUDGE

- - -

March 13, 2017

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Deposition of JOHN R. WAGNER, M.D., held at Marriott Melville, 1350 Old Walt Whitman Road, Melville, New York, commencing at 9:04 a.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

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9:04 a.m.

Melville, New York

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JOHN R. WAGNER, M.D., the Witness herein, having been first duly sworn by a Notary Public in and of the State of New York, was examined and testified as follows:

EXAMINATION BY

MR. AYLSTOCK:

Q. Good morning, Dr. Wagner. How are you?

A. Good morning.

Q. Have you ever given a deposition before?

A. Yes.

Q. So you're familiar with the general principles of it. I'll ask a question and you'll answer it to the best of your ability?

A. Yes.

Q. If you don't understand a question, please let me know so I can rephrase the question because that way I can get clear answers to hopefully clear questions, okay?

A. Okay.

Q. I'm going to hand you first Exhibit 1 to the deposition. It's the notice.

(Exhibit Wagner 1, Notice to Take Deposition of John Wagner, M.D., dated March 1, 2017, was marked for identification, as of this date.)

BY MR. AYLSTOCK:

Q. Have you seen that document before, Doctor?

A. I may have. Not that I recall though.

Q. If you turn a few pages, you'll see a list of things that are requested to be brought to the deposition.

Are you familiar with that list?

A. Yes.

Q. Have you brought documents responsive to the deposition notice with you today?

MS. KABBASH: Bryan, I'll just represent to you that we have brought on the flash drive that I've provided to you all the materials listed on Dr. Wagner's reliance list, and we also have for you an invoice from December 2016 and January 2017 which is the only invoice that Dr. Wagner has provided to us so far.

MR. AYLSTOCK: Okay. We'll mark the flash drive as Exhibit 2 to the deposition and the invoice as Exhibit 3 to the deposition.

(Exhibit Wagner 2, flash drive containing documents, was marked for identification, as of this date.)

(Exhibit Wagner 3, John Wagner, M.D., invoice December 2016/January 2017, was marked for identification, as of this date.)

BY MR. AYLSTOCK:

Q. So, it's been represented to me by counsel that on the flash drive are the documents on your reliance list?

A. Yes.
Q. Did you save this to the flash drive, or did counsel save this to the flash drive?
A. Counsel did.
MR. AYLSTOCK: Mark as Exhibit 4 to the deposition a document entitled "John Wagner General Reliance List."
(Exhibit Wagner 4, John Wagner General Reliance List in Addition to Materials Referenced in Report MDL Wave 4, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. Are you familiar with that document?
A. I think I am.
Q. And then as Exhibit 5 there's a supplemental general reliance list. That was also provided to me by counsel.
Are you familiar with that document?
A. Yes.
(Exhibit Wagner 5, John Wagner

Supplemental General Reliance List in Addition to Materials Referenced in Report MDL Wave 4, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. Let me ask you do you know why your reliance list was supplemented?
A. No.
Q. Do you know the differences between Exhibit 4 and Exhibit 5?
A. One is the original, one is the supplement.
Q. Okay. But do you know what is different between the two documents?
A. No, I don't.
Q. Were you involved in what was added or supplemented on Exhibit 5 from Exhibit 4?
A. No.
Q. Did you have any involvement whatsoever in creating the reliance list or the supplemental general reliance list?
A. I was basically involved in creating my reliance list as also -- as it

relates to my general report, and I'm more familiar with the studies that are cited in my general report. And having looked at quickly what's on the supplement list, and I didn't look at what was on the original, but what's on the supplement list, I have reviewed some of those documents.
Q. Okay. By calling it a reliance list, I take it these are the documents, studies and materials that you rely upon for your opinions in this case?
A. This is part of the literature that I'm relying on, yes.
MR. AYLSTOCK: Let me just make a statement for the record.
Before the deposition started, Ms. Kabbash and I had a conversation, and just so it's clear to anybody reading it, this deposition is going to be related to the TVT Retropubic portions of your report and those are the questions that I'll be focusing on today.

MS. KABBASH: Correct, that's our understanding.
BY MR. AYLSTOCK:
Q. Let me go back to your invoice.
According to Exhibit 3, you have billed and been paid thus far $10,850 by Ethicon; is that correct?
A. Yes.
Q. Have you provided any further invoices since January of 2017 to Ethicon or its counsel?
A. I provided an invoice for the first two weeks of February, and I have not provided an invoice for the last two weeks of February.
Q. Do you recall how much you billed for the first two weeks of February?
A. The hours were approximately ten, somewhere in the range of ten, I believe.
Q. Okay. And then how many hours have you spent on any of these cases listed here on Exhibit 3 since your last

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invoice?
A. I would say roughly, and this is roughly 'cause I have not added it up, but probably the last two weeks of February, maybe eight hours. And I would estimate the first 12 days of March here, probably about 12 to 15, but I haven't added them up. I have a record at home that I keep.
MR. AYLSTOCK: Counsel, I request both the invoice that wasn't provided as well as the record that he's keeping.
MS. KABBASH: To be clear, it was sort of an e-mail with some hours in it. It has not yet been put into a formal invoice like that, and we were planning on generating one after we had the remainder of February hours. So that's why you don't have an invoice for the first part of February, but I think he's provided the best estimate he can.
When we get another invoice, we'll provide it to you.

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MR. AYLSTOCK: I'd request the e-mail which reflected it as well that you referenced.
MS. KABBASH: Okay.
BY MR. AYLSTOCK:
Q. In Exhibit 3 you note that you spent six hours drafting and editing the expert report.
Do you see that?
A. Yes.
MR. AYLSTOCK: Let me mark Exhibit 6 I believe is your expert report provided for the Wave 4 cases.
(Exhibit Wagner 6, Expert Report of John R. Wagner, M.D., dated January 31, 2017, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. The six hours that you spent drafting and editing the report for it says "general" here on Exhibit 3, is that the time and effort reflected in Exhibit 6, your Expert Report of John R. Wagner?

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A. In a sense. It was actually the time I spent specifically related to that document.
Q. Okay.
A. I had done reviews of cases prior to that and had done some general reviews of the literature given to me as sort of background 'cause I was just starting out. I was trying to generate some background information. So, some of that effort went into this product. But specifically what, if anything else, billing for in that was actually the time it took to create this product after doing that review.
Q. And by "this product," you're talking about Exhibit 6, Expert Report of John R. Wagner; is that correct?
A. Yes.
Q. You mentioned reviewing some other cases.
A. Yes.
Q. You have three other cases reflected in Exhibit 3, your invoice:

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Judy Stahl, Kim Adkins and Tammy Mayes.
Are those the cases that you're referring to?
A. Yes, it is.
Q. Have you reviewed any other individual cases with regard to your work as an expert for Ethicon?
A. No.
Q. Did you bill for your time in reviewing the general literature that you referred to earlier in preparation for the drafting and editing of your general report as reflected in Exhibit 6?
A. It would be best described by me as trying to get a handle on what the issues were, and they were more focused on the specific cases than my general report initially. I could have organized it differently, but I think that my edit expert report was the time spent actually doing that expert report.
Q. And so, is it fair to say that your general literature review would be reflected in the hours spent for in the

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Tammy Mayes case, Kim Adkins case and Judy Stahl case?
A. Yes, I was reviewing those cases and the literature that was associated with them, which overlapped some of the literature in my expert report?
Q. In other words, Exhibit 3 reflects, at least as of the end of January '17, all of the time that you spent reviewing general literature, reviewing any of the materials on your reliance list or supplemental reliance list, and reviewing the specific cases that Ethicon asked you to review; is that correct?
A. Up to that point, correct.
Q. And you billed for all of your time with that, correct?
A. Yes.
Q. How much do you charge an hour?
A. I believe it's 350 an hour, yes.
Q. How much time did you spend preparing for today, this deposition today?

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A. I would say that most of the hours that I spent in the last two weeks are geared towards preparing for this deposition today.
Q. Okay. And you had mentioned that you've given previous depositions; is that correct?
A. Correct.
Q. Have you ever given any previous depositions for Johnson & Johnson or Ethicon in the capacity of an expert witness?
A. No.
Q. When were you first retained by Ethicon to give testimony in the pelvic mesh litigation?
A. I was first contacted in mid-December and agreed to become an expert for them shortly thereafter.
Q. Mid-December 2016; is that correct?
A. Correct.
Q. Who contacted you?
A. Ms. Kabbash.

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Q. Have you given depositions in any other pelvic mesh cases as a treating physician?
A. Yes.
Q. What case or cases?
A. I don't remember the patient's name, but it was a case from about four or five years ago, maybe less, maybe four years ago, that went to trial and we were successful. It was a case involving placement of a Prolift mesh.
MS. KABBASH: Could I just clarify one thing?
Can you just clarify if that was a case in this pelvic mesh litigation? Because I don't know.
MR. AYLSTOCK: Yes, I was going to follow up.
BY MR. AYLSTOCK:
Q. So, you said "we were successful."
Were you a defendant in that case?
A. I was.

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Q. And was that a medical malpractice case?
A. It was.
Q. Where did it go to trial?
A. In -- in Queens. It wasn't Riverhead.
Q. Who was your lawyer?
A. I don't remember.
And I should probably correct my last answer. I think this did go to trial in Riverhead. I had another case that was tried in Queens which involved a baby. I think that the mesh case was in Riverhead.
I don't remember my attorney.
Q. Were you sued personally?
A. Yes. Well, my corporation was sued, or -- correct.
Q. What is your corporation?
A. WGM Obstetrics and Gynecology.
Q. Is that a New York corporation?
A. Yes.
Q. I guess the W stands for Wagner?
A. Yes.
Q. And G and M are your partners in

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the OB-GYN practice?
A. The initial partners, correct.
Q. Who was G and who was M?
A. Goldman is the G and Morris was the M.
Q. Do you know who the plaintiff's lawyer was?
A. No.
Q. Was he from New York?
A. I believe so.
Q. Do you have a copy of your deposition from that case?
A. No.
Q. Was it your corporate lawyer who defended you in that case, or did you have an insurance lawyer?
A. It was a lawyer assigned by my insurance company.
Q. Who was your insurance company at the time?
A. At the time of the lawsuit, I believe it was MLIMIC, but that wasn't my insurance company at the time, but I was covered under MLIMIC at the time of the

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occurrence.
Q. Was Ethicon also a defendant in that case, or was it solely you or your practice?
A. It was solely myself and my practice.
Q. And what were the allegations against you in that case?
A. That the mesh was placed in an improper anatomic location.
Q. Was it a total Prolift or an anterior or posterior?
A. It was a total Prolift.
Q. Were they alleging that you did not do a full thickness dissection?
A. No.
Q. What was the nature of the allegation as far as placement?
A. They were alleging that it was placed in the abdominal cavity and not the retroperitoneal cavity.
Q. Did you perform that implantation procedure in accordance with the Prolift instructions for use?

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A. I believe so. Although there might be some minor surgical modifications that I would have made individually in terms of trimming the mesh and other areas that might not be in the specific instructions for use.
Q. What was the approximate date you placed the Prolift?
A. Probably about seven or eight years ago, but that truly is my best guess.
Q. And your best estimation as to when it went to trial in Riverhead?
A. About four to five years ago. And again, I really have to hesitate that that's a bit of a guess.
Q. Was it before or after the July 13th, 2011 FDA safety alert on Prolift?
A. I believe the surgery was probably performed before that time, and the lawsuit commenced and the trial took place after that time, but I have to hesitate that my dates on that are not certain.

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Q. Would you be able to give me a better answer if you were able to look at your files in your office on that case?
A. No.
Q. Why is that?
A. I don't keep any files on those cases once they are adjudicated.
Q. Okay. How would you find out who the patient was?
A. I'd probably have to call MLIMIC.
Q. Who is your contact at MLIMIC?
A. Wait, that's not exactly -- that's not true.
I do keep a copy of a summary of my malpractice history that I update periodically that I give to insurance companies every year, and that would include that case, at least by initials. It would have the patient's initials in it.
Q. And the date that it was adjudicated and so forth?
A. Roughly, yes. That would be my

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only record.
Q. And that would be something easy for you to ascertain?
A. Yes, it would be very easy for me to ascertain that.
MR. AYLSTOCK: For the record, I'd request a copy of that document to be provided.
BY MR. AYLSTOCK:
Q. All right. Just so the record is clear, the Prolift is a pelvic mesh polypropylene device, correct?
A. Yes, it is.
Q. And it's a polypropylene device, it's made out of polypropylene?
A. It's made out of polypropylene, yes.
Q. Was this the regular Prolift or the Prolift+M?
A. If my memory serves correctly, I believe it was the regular Prolift.
Q. Did you use both products?
A. I did.
Q. We'll get to that at some later

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point.
MS. KABBASH: Not today.
MR. AYLSTOCK: I'm trying to focus on the retropubic, and I'm going down things I didn't expect to go in. So I'll try to get back to my outline here.
BY MR. AYLSTOCK:
Q. Was there any other depositions you've given as simply a treating physician for any of the pelvic mesh cases anywhere; in other words, not as a defendant, but just as a treating doctor?
A. No.
Q. I hand you Exhibit 7 which is your CV.
(Exhibit Wagner 7, Curriculum Vitae of John R. Wagner, M.D., was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. Is this a copy of your current CV, Dr. Wagner?
A. Yes.

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Q. Is it accurate and up to date?
A. Yes.
Q. There's some blacked out items here.
I don't need phone numbers, personal cellphones or so forth, but what was blacked out?
A. It was my office address and phone numbers, my date of birth, and personal information about marital status and number of children.
Q. Got it.
So, what is your date of birth?
A. July 2nd, 1961.
Q. You're board certified in two different specialties; is that correct?
A. Yes.
Q. Did you pass those board certification exams the first time?
A. Yes.
Q. It shows here I guess you completed your residency in 1991; is that right?
A. Yes.

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Q. And you have privileges at what hospitals?
A. I have privileges at Huntington Hospital and Winthrop University Hospital.
Q. Have you ever had any privileges suspended or denied?
A. No.
Q. It says here you also work with Hofstra University; is that right?
A. Yes.
Q. And what is your role, what do you do for them?
A. The role is technically clinical associate professor, and essentially what that involves is mentoring a medical student on a yearly basis.
Q. So this is a medical student that comes to your office here on Long Island?
A. Yes, and to the hospital and to the operating room.
Q. Do you go into Hofstra and teach students in a classroom setting?
A. No.

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Q. Have you ever done that?
A. I've taught students and residents in a classroom setting at my hospital.
Q. How long ago was that?
A. Within the last two years. They've had a more robust family practice medical student presence, and they have a series of lectures that are given to them, and I participate in that lecture series.
Q. So you'll just give a lecture from time to time to students who come to the hospital?
A. And family practice residents.
Q. Okay.
A. Correct.
Q. Is that the extent of your involvement with Hofstra University as clinical associate professor?
A. It is.
Q. Next on your CV you list "Consultant/Proctor."
Do you see that?
A. Yes.

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Q. It looks like right after your residency, you began as a consultant for Wyeth-Ayerst, a pharmaceutical company; is that right?
A. Correct.
Q. That lasted for about ten years?
A. It did.
Q. And then in 2002, it looks like as that was winding down you started as a consultant/proctor for Ethicon Gynecare; is that right?
A. Correct.
Q. And that lasted for 12 years, right?
A. Yes.
Q. Just ended a couple years ago?
A. Correct.
Q. Why did that end?
A. I don't think there's a particular reason that I'm aware of.
Q. Did they just let you know that they weren't going to need your services anymore?
A. This was more of an ad hoc thing

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with Ethicon and Gynecare. I would be called upon occasionally to teach a surgeon who was brought to my hospital or to go to another hospital to assist a surgeon who was learning one of -- to use one of their products.
I recall once that I was involved in a cadaver course, involved more teaching the TVT Obturator, the TVT Secur, and the TVT Retropubic. It was -- wasn't a -- it was more of a as-needed relationship.
Q. Who was your contact at Ethicon?
A. It was Edward Lynch.
Q. Do you know what department he was in?
A. He was my sales rep.
Q. Would an Ethicon sales rep attend these surgeries with you for the pelvic -- Ethicon pelvic mesh products, including the TVT Retropubic?
A. He might be there sort of shepherding the doctor, but he was not necessarily in the operating room.

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Q. Okay. Shepherding the doctor, what do you mean by that?
A. Bringing -- bringing them into the hospital, introducing them to me.
Q. Okay. What about when you were just doing your own implantations of the TVT products, would there be a sales rep in the operating room for that?
A. At the very beginning when I first put a Prolift in, I do remember him being there for the first couple of cases, but not after that.
Q. The malpractice case against you involving the Prolift, what were the injuries that were suffered by that patient of yours?
MS. KABBASH: Objection to form. You can answer.
A. She had a Prolift placed and postoperatively developed an acute small bowel obstruction, and she was re-explored. At the time of the re-exploration, the top of the vagina had a loop of small bowel that was adherent to

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it, and when the Prolift was placed, it re-oriented the top of the vagina back to its normal anatomic position, and that re-orientation caused a kink in the small bowel that obstructed it. So she required surgery to unkink the small bowel, or essentially lyse that adhesion that was on the abdominal side of the vagina.

Q. Did you perform that subsequent surgery?

A. I assisted at the subsequent surgery.

Q. Was there mesh involved?

A. There was mesh placed with the Prolift.

Q. And when the subsequent surgery had to unkink the bowel, did you see mesh involved?

A. We did see mesh because we took a dime-sized, nickel-sized segment of vaginal epithelium off the top of the vagina and left it attached to the bowel so that when we were done lysing that adhesion and freeing up that small bowel,

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there was a circular defect at the top of the vagina and that piece of vaginal epithelium was still attached to the bowel.

Q. Did you remove mesh in that surgery?

A. No.

Q. Would you consider that an adverse event from the Prolift?

MS. KABBASH: Objection to form.

A. I considered that an adverse event from her repair.

Q. And her repair using the Prolift, correct?

MS. KABBASH: Objection.

THE WITNESS: Would you like me to answer?

MS. KABBASH: You can answer it.

A. The question was what again?

Q. You said an adverse event from the repair, and I'm just trying to clarify from the repair in correcting her pelvic organ prolapse, correct?

A. Correct.

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Q. With the Prolift?

A. We used Prolift to fix the support defect, but based on what happened with her, anything that we had done to replace the vagina to its normal position probably would have kinked that bowel.

Q. Did you report that adverse event to Ethicon?

A. No.

Q. Did you report it to the FDA?

A. No.

Q. Back to your CV.

It looks like you've also been consultant or proctor to various other pharmaceutical medical device companies continuously since the end of your residency, correct?

A. Yes.

Q. And the other companies you've consulted for include GlaxoSmithKline, correct?

A. Some of these were not surgical consults. I was part of their expert panels for giving lectures.

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So for instance, Wyeth was -- I was generally one of their experts on hormone replacement. At GlaxoSmithKline, I was their expert on medical management of herpes. Genetech it was osteoporosis management. Same with Warner Chilcott.

So really the only surgical companies involved were Ethicon, Covidien, and Intuitive Surgical.

Q. And for all of these engagements with the pharmaceutical and medical device industry since 1992 you've been paid by them, correct?

A. For work that was done, correct.

Q. Initiative Surgical, what is that?

A. That is a typographical error that I just noticed. It should be Intuitive Surgical.

Q. And what kind of company is that?

A. That is the company that makes the surgical robot.

Q. Did you ever, with Covidien, did

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you ever implant any of their pelvic mesh products?
A. I don't think so. I wasn't really aware that Covidien had a pelvic mesh product, but I may be wrong on that.
Q. You mentioned the robotic surgery with Intuitive.
Do you do robotic surgeries to fix pelvic floor defects?
A. Yes.
Q. Do you do them to fix stress urinary incontinence with pelvic mesh?
MS. KABBASH: Objection to form.
You said "with pelvic mesh" at the end. I'm sorry, I just need a clarification.
Do you mean does he use robotic surgery to implant pelvic mesh?
MR. AYLSTOCK: That's a better question than I just asked.
MS. KABBASH: I just wanted to make sure.
MR. AYLSTOCK: So I'll restate it.

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MS. KABBASH: Okay.
BY MR. AYLSTOCK:
Q. Do you use this robotic surgery to implant pelvic mesh?
A. Yes.
Q. And with the robot, you don't go through the vagina, correct?
A. Correct.
Q. You go through the abdomen?
A. Correct.
Q. And the robotic surgery is a minimally invasive surgery, correct?
A. Yes. Although minimally invasive is sort of a relative term.
Q. Agreed.
When did you start doing robotic surgeries to implant pelvic mesh?
A. Probably about 2014. I was doing laparoscopic surgery to implant pelvic mesh prior to that.
Q. And that's the Covidien notation on your CV?
A. No. Covidien is more -- it was a single incision laparoscopy. I was

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involved with them teaching single port laparoscopic surgery.
Q. Okay. Why did you begin implanting pelvic mesh either laparoscopically or using the robotic surgery?
A. Because relatively speaking, it was much more minimally invasive than doing it through an open abdominal incision.
Q. Did you do the robotic or laparoscopic mesh surgery in situations where another method of implantation could have been through the vagina?
A. If I could answer that in a general, I'll try.
You can place mesh transvaginally or transabdominally, and there are situations where I think the transvaginal approach might be best and situations where the transabdominal approach might be best for a given patient.
Q. What things go into your

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determination as to whether you recommend transabdominal as opposed to transvaginal for a mesh implantation?
A. In general, and this would be my current thinking, in someone who requires a mesh implant, we would probably prefer to place it abdominally because the complication rate is probably lower.
On the other hand, there are people who can't tolerate an abdominal operation, because of patient factors or it might be particularly high risk for an abdominal risk because of patient factors, who need to have that mesh placed and therefore need to have it placed vaginally. And then there are people who may have a very small isolated recurrent vaginal defect who might be a good candidate to approach it vaginally because the defect is relatively small.
Q. So, all else being equal, you prefer the abdominal approach to placement of pelvic mesh because, in your experience, the rate of adverse events is

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lower?
MS. KABBASH: Objection to form.
You can answer.
A. Again, I think that it depends on whether the patient needs mesh or not. I think when I think about these terms, I think does this patient need a mesh or not or can she get by with a traditional repair. And then if I decide that yes, she's at high risk for some reason and needs a mesh implant, should I place it vaginally or abdominally has a number of factors.
If I think a patient requires a very large mesh implant of the anterior apical and posterior walls, I would prefer to place that abdominally if she is a candidate for abdominal surgery.
Q. And that's because in your experience, the rate of adverse events is lower abdominally as opposed to transvaginally, correct?
A. In my experience, and as well as, you know, the experience I think of

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others in the literature and colleagues, by avoiding vaginal incisions, you seem to minimize the risk of complications related to the mesh.
Q. Can you do a -- you mentioned a patient not being a candidate for traditional repair.
Do you still do traditional repair for stress urinary incontinence?
MS. KABBASH: Objection to form.
You can answer.
A. If by traditional you mean a Burch colposuspension or an MMK or a pubovaginal sling or a Pereyra or a Stamey, by and large, no. I think that I used to do a lot Burches and Pereyra's. Those were my procedures of choice, but the TVT product and line of products has really revolutionized that procedure.
Q. Let me just ask you directly.
You still do Burch procedures from time to time, correct?
A. I think I've done one Burch in the last two years or three years.

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Q. And what other non-mesh procedures can be done for the treatment of SUI?
A. Well, traditionally, we used to do anterior repairs with a Kelly plication. We would do a Burch procedure. For recurrent stress incontinence, we would often do a pubovaginal sling retropubically with either autologous graft or synthetic material. And then you had your needle suspension procedures, like the Pereyra and the Stamey.
Q. You can do a Burch procedure laparoscopically, correct?
A. No, I've never done that.
Q. You haven't seen it done?
A. I've seen it done. I've never done one.
Q. But it's possible, doctors can do them, correct?
A. You can do a Burch procedure laparoscopically or robotic or via an open incision.
Q. Let's move now to your

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publications on your CV.
How many of these, when you say publications or national presentations, how many articles have you had published in the peer-reviewed medical literature?
A. Four, I think.
Q. Does that include abstracts that were presented via poster at a conference?
A. No.
Q. And then you've had a number of presentations in addition to the peer-reviewed publications, correct?
A. Correct.
Q. Do any of these publications or presentations involve the treatment of stress urinary incontinence?
A. No.
Q. So you've never had a publication or presentation on the treatment of stress urinary incontinence, correct?
A. Not at a national meeting.
Q. And the other ones you've had were as a consultant or a proctor for

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Ethicon or Johnson & Johnson, correct?
A. Either in that role or giving grand rounds at other institutions, I would have the opportunity to talk about stress incontinence and the placement of slings.
Q. But in none of those instances did you feel it appropriate that the level of the presentation rose to put on your CV, correct?
MS. KABBASH: Objection to form. You could answer.
A. Well, I started recording lectures and presentations in that regard only since 2014.
Q. And none of them are reflected on your CV, correct?
A. No, they are reflected on my CV.
Q. None of the presentations involving stress urinary incontinence that you gave in grand rounds are, correct?
A. That is correct.
Q. And describe for the jury what you mean by "grand rounds."

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A. Typically most hospitals and most departments have monthly or twice-monthly or weekly formal lectures that take place for education purposes, and various people are invited to give these talks.
Q. Are they recorded?
A. Sometimes.
Q. They're not peer-reviewed talks, correct?
A. They are not peer-reviewed talks.
Q. Let me show you Exhibit 8, please.
(Exhibit Wagner 8, Wagner article titled Vaginal Repair of Symptomatic Pelvic Organ Prolapse Using Polypropylene Mesh, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. Okay. This is I think reflected on your CV of your presentation at the American College of Obstetrics and Gynecology, the meeting in 2006, right?

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A. Yes. I haven't seen this for a while.
Q. Well, we'll go through it.
This is your -- I guess this was a poster presentation at that meeting, correct?
A. Correct.
Q. And a poster is not a peer-reviewed publication, correct?
A. It's peer-reviewed in the sense that people submit these things to an annual meeting and they have to be selected by the people running the meeting, the people that are in charge.
Q. But it's not subject to the typical peer review of a journal or anything like that?
A. It is not, no.
Q. Did you present on this poster that you gave or you --
MR. AYLSTOCK: Let me strike that.
Q. Was this poster presented at this meeting in 2006?

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A. Yes.
Q. And did you present on your findings at that meeting?
A. Yes.
Q. Do you know whether that was recorded?
A. I don't believe that it was.
Q. Was this a situation where you kind of stood by the poster and anybody that showed up could ask you questions and you talked about it, or did you actually present this in a meeting more formal way?
A. No, this was more the former, not the latter.
Q. In other words, this was a poster that you -- I've been to some of these meetings. So, there are lots of posters and then the author of the presentation stands by the poster and if doctors are interested, they can come ask questions and you can talk about the poster, correct?
A. Correct.
Q. This wasn't something where you

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stood up in front of hundreds of doctors at a meeting and gave your findings, correct?
A. It was not that.
Q. Now, the title of this is "Initial Results of a Modified Proximal Bladder Neck Sling in Patients At Higher-Risk For Failure," correct?
A. Correct.
Q. You would agree that the TVT Retropubic is made of polypropylene mesh, correct?
A. Correct.
Q. Now, because this -- well, was this article ever published in a peer review journal?
A. No.
Q. Did you ever submit it for publication?
A. No.
Q. Why not?
A. Didn't have the time or want or desire, I guess.
Q. And at the time in 2006,

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according to your CV, you were a consultant/proctor for Ethicon Gynecare, correct?
A. Correct.
Q. Is there anywhere disclosed on this poster?
A. No.
MS. KABBASH: Objection to form.
BY MR. AYLSTOCK:
Q. Had you submitted this for publication in peer review journal, would you have made that disclosure to the journal?
MS. KABBASH: Objection.
A. I'm not sure what the rules for disclosure were back in 2006. I know that if I submitted the same poster today, they would require me to list my con -- my possible conflicts of interest, and I'm not sure that it was required of a written article back then, and it certainly wasn't a requirement that they asked for here in 2006.
Q. Sure.

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How did this study come to be? Was Ethicon involved in this at all?
A. No.
MS. KABBASH: Objection; lack of foundation.
BY MR. AYLSTOCK:
Q. Did you discuss this study with Mr. Lynch or anybody else at Ethicon before presenting it?
A. No.
Q. What type of polypropylene mesh did you use in this study?
A. It was the Gynecare sheet of mesh.
Q. The Prolene Soft or Prolene?
A. Prolene.
Q. I take it you kept the materials surrounding the study electronically or in a folder or something?
A. No.
Q. To your knowledge, is there any, other than this document, Exhibit 8 that we just looked at that you hadn't seen in a while, is there anywhere where the data

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that underlie the study was stored?
A. I don't think I kept it for more than about a year or so.
Q. Okay. Did you ever undertake any, or begin any other type of studies involving the Prolene polypropylene mesh?
A. No.
Q. The Prolene mesh sheets that you got, you understand Prolene's the same mesh that's in the TVT Retropubic sling, correct?
A. Correct.
Q. And the mesh, this was a flat sheet of mesh that you used in this study?
A. It was a flat sheet of mesh that I used and then I cut out patches, essentially, and place them in the various compartments.
Q. Okay. Who provided the Prolene mesh that was used in this paper?
A. My hospital.
Q. Do you know whether it was paid for by Ethicon, or they just gave you the sheets of mesh to use?

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A. I'm sure the hospital paid for the sheets of mesh.
Q. Okay. Did you ever submit to Ethicon or any other mesh manufacturer a proposal for study?
A. No.
Q. Okay. So, this particular poster was the result of just your independent curiosity as to how the Prolene mesh would perform in the human body?
A. Not exactly. Back in 2005, essentially, is when these cases were done. There just wasn't a lot of data on using polypropylene mesh to repair other vaginal defects. There was data on using polypropylene slings to treat incontinence, but the data for other defects wasn't there, and this was when we were graduating into thinking that we could repair other defects with mesh also. And this represented, essentially, my initial experience fixing 53 defects, it says here, in 33 vaginal procedures. It

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was publishing my initial experience is essentially what it was, and there wasn't a lot of data out there at that time.
Q. Okay. Before you go about implanting a medical product in a man or a woman, why is it important to you that there be clinical data to support that product?
MS. KABBASH: Objection to form. You can answer.
A. There was -- I'm confused by that question. Could you repeat that question to me again?
Q. Sure.
You testified earlier that you wanted to perform the study because there wasn't a lot of clinical data out there on the use of this Prolene polypropylene mesh for the particular defects, and my question was why is it important to you that there be clinical data before you implant a medical device in a woman in this case?
MS. KABBASH: Objection to form.

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A. There wasn't a lot of published data on using polypropylene mesh to fix these types of defects, but these types of defects were being fixed with polypropylene mesh by a number of different pelvic reconstructive surgeons that I knew of personally, and none of them had really published large volumes of data at this point. It was more case reports and small series. And this was basically an attempt to publicize our initial experience with this approach.
Q. Okay. And with the Prolene polypropylene mesh, correct?
A. Correct.
Q. Now, your paper here looks at 31 patients, correct?
A. Yes, 31 patients, yes.
Q. And you report that the rate of mesh erosion using this Prolene mesh was 3.7 percent, 2 out of the 53 had mesh erosion, correct?
A. Correct.
Q. And then a mesh extrusion rate

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was 11.3 percent; 6 out of the 53 had extrusion, correct?
A. Correct.
Q. What's the difference as it relates in this paper between mesh erosion and mesh extrusion?
A. I define an erosion as visible mesh with an epithelial defect and an extrusion as visible mesh without an obvious epithelial defect. That -- the definition of both of those remain somewhat ill-defined even today, but that was my opinion as to how to characterize them back in 2006.
Q. Okay. And what do you mean by "epithelial defect"?
A. Essentially with these repairs, sometimes you'll see normal vaginal epithelial and a tuft of mesh protruding through that, what appears to be an intact epithelial. In other words, you'll see a true epithelial defect with a visible patch of mesh, and I separated those two out into an erosion and an extrusion.

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I think based on today's definition, we would call all of those extrusions with an erosion referring more to something that's more chronic and into a hollow organ such as the bladder or the urethra or something.

Q. So, if you add up the two, as you defined back then erosion and extrusion, your overall erosion rate, as you would call it today, was 15 percent using the Prolene mesh, correct?

A. Correct.

Q. And you followed these patients, this particular subset of 31 patients was seen by you over 12 months?

A. These were people that I had followed over the last 12 months and operated on during that 12-month period.

Q. And then they came back to you at some point during that 12-month period for another examination to determine how the mesh was performing?

A. Yes.

Q. Were they all seen at exactly

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one year, or were some seen before one year was up?

A. I think this was an average amount of time of about a year-and-a-half. So some were seen for shorter period of time, some were seen for longer period of time.

Q. When you were presenting this poster at the conference, did anybody from Ethicon come and talk to you about it?

A. Not that I recall, no.

Q. And did anybody contact you following that presentation from Ethicon to discuss the findings that you had using Prolene mesh?

A. Not that I recall. I would have to imagine that my Ethicon rep at the time was probably aware that I had presented this, but I don't recall any specific conversations.

Q. Other than perhaps a comment from your sales representative, no scientist or medical doctor or professional education person ever

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contacted you about your particular results using the same Prolene mesh that's in the TVT Retropubic, correct?

A. Correct.

Q. And since the study over 12 months, have you continued to follow these, or did you continue the study beyond the 12 months as reflected here, or was that the last time you endeavored to follow up on these particular patients for publication purposes?

A. I never followed up with those patients for publication purposes. Most of them were patients that were in my practice already, so I followed them for a while.

Very shortly after that, I stopped doing this and I started using the Prolift system.

Q. Okay. And did you begin using the Prolift system based in part on your findings using the polypropylene mesh here? I'm sorry, here with the 31 patients reflected in this study?

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A. No. I think I started using the Prolift system because I felt that it was less invasive than what I was doing in terms of these mesh patches, and it was also a system that could be tightened or loosened in the operating room to better fit each patient's defect and set the mesh in a tension-free manner.

Q. Did the mesh you used in this particular presentation have arms? Or how was it shaped?

A. It was shaped the way I cut it.

Q. Were they all shaped exactly the same, or were there varying shapes?

A. No, I cut three different kinds of mesh: one for the anterior compartment, one for the apical compartment, and one for the posterior compartment.

Q. And did any of those have arms attached?

A. No.

Q. The results report on 31 patients.

Were there more than 31 patients

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in your practice upon whom you operated with this particular method of implantation with the polypropylene sheet mesh?
A. Yes.
Q. So how were these 31 selected?
A. When I did the study, I just went back to when I started doing my first mesh repair. Or I should say my first mesh augmented repair, and I just took it up to that current time, developed the data, submitted it. But I was still doing those mesh repairs during the time I was collecting the data and submitting it and for a short period of time afterwards.
Q. So, do you know whether any of these have been lost to follow-up?
A. I wasn't trying to follow up with them. So technically, I guess they're all lost to follow-up.
Q. Okay. So you're in no position to report on anything beyond the 12 months reflected here as to whether they had subsequently needed to have additional

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surgeries, revisions and so forth, correct?
A. I was not attempting to do a long-term follow-up.
I can tell you the majority of these patients, probably two-thirds to three-quarters, were patients of my practice and probably still are.
Q. You'd be speculating about that?
A. But I would be speculating.
Q. Okay. So, other than this particular presentation given on a poster at this meeting, have you done any other studies on polypropylene mesh for use in the female pelvis?
A. No, nothing that's been submitted.
Q. Have you done them where it hasn't been submitted?
A. We are collecting data on patients with anterior mesh repairs with one of my residents now.
Q. Are these repairs done robotically?

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A. No, these are vaginal mesh repairs.
Q. And why are you collecting that data?
A. Because we use a different vaginal incision, a distal transverse incision, to access the compartment in the vagina where the bladder lies and lay the mesh in through that incision, and the advantage that we found is that the incision is away from the location of the mesh and we have not had an erosion or extrusion of those mesh repairs to date.
Q. That's a vaginal incision, correct?
A. It's a vaginal incision.
Q. Are you doing that in conjunction with any particular manufacturer of mesh?
A. No.
Q. Have you submitted a request for funding to any mesh manufacturer for your efforts?
A. No.

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Q. Do you have any preliminary finding based upon your review so far?
A. My preliminary findings are based on my surgical experience that we haven't seen an anterior mesh erosion in three or four years since we started doing this approach.
Q. And that particular mesh that's being used that was used in those patients was what?
A. I don't believe it's uniform. It was Prolift for a while. We've had some Coloplast products that we've put in. I'm pretty sure that there's even some Boston Scientific Uphold meshes that we've placed.
Q. You know that the Prolift mesh that was used by Ethicon is not the same mesh that's used in the TVT Retropubic, correct?
A. The Prolift mesh has -- you're not just talking about straight Prolift. You're talking about -- I mean, not Prolift+M. You're talking straight

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Prolift.
Q. I'm talking about the polypropylene Prolift mesh.
A. It's a different pore size, but it's the same material.
Q. It's made out of polypropylene, but it's lighter weight, correct?
MS. KABBASH: Objection to form.
A. It has a larger pore size, but the weight of the material is the same.
Q. Do you know whether the individual strands of polypropylene that are woven are the same thickness or diameter between the TVT Retropubic or Prolift?
A. I'm not aware of the size of the actual strands. I'm aware of the pore size.
Q. And the Prolift has a larger pore size, correct?
A. The Prolift has a larger pore size, yes, it does.
Q. Have you seen any studies or materials that reflect the weight of the

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Prolift as it relates to the TVT Retropubic polypropylene mesh?
A. Weight would be a function of how much polypropylene you have. I mean, if you have a small piece of it, the weight of that's going to be small. If you have a large piece of it, the weight's going to be large.
I'm not sure I understand the question.
Q. Okay. We'll get back to that.
So, have we now -- you've also submitted some other materials for peer review that have been published in medical journals, correct?
A. I have.
Q. Why is it important to disclose any financial relationships with any manufacturers when one is publishing in peer-reviewed literature?
A. People want to know what potential biases somebody might have in presenting data. So the logic is to state your potential conflicts of interest at

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the beginning of any talk you give now, as well as any presentation, as well as any publication.
I think that that is pretty much a uniform standard that's come into play in the last five years or so.
Q. And that's because whenever funding comes into play, there's at least a potential for bias, correct?
A. I'm not sure the exact reason other than being up front and honest. I guess there must be funding involved. It always comes down to money at some point, but I never been somebody who ever requested funds for anything, but I do like to know if somebody's talking to me if they work for somebody.
Q. And that's because that introduces the potential for bias, correct?
A. It could. Theoretically though if you're putting it out there and acknowledging it, you're allowing people to question you on that and ultimately

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eliminating any specter of bias. I think the purpose of the conflict of interest is to eliminate the specter of bias.
Q. It's important to be up front and honest when it comes to funding sources and so forth when you're a study author, correct?
MS. KABBASH: Objection to form.
A. It becomes important to be up-front and honest, period.
Q. I'd agree with that.
A. It's the Ten Commandments.
MS. KABBASH: Let's not get into that today.
BY MR. AYLSTOCK:
Q. But especially when it comes into play with regard to medical journal articles, correct?
A. I think with any medical --
MS. KABBASH: Objection to form.
A. -- presentation it's important to be up front and honest.
Q. Now, have you ever been involved, other than the materials

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reflected in your CV, in a study design?
A. No.
Q. Do you consider yourself an expert in designing studies?
A. It was part of my board certification in 2014. It was like one-sixth of what we were required to know. So I feel I have a lot more knowledge of that than I did three or four years ago.
Q. Okay. And in gaining that knowledge, you've come to understand that it's important when designing a study that the study author should not have a financial interest in the outcome of the study, correct?
MS. KABBASH: I just want to state a standing objection that the issue --
MR. AYLSTOCK: You can object to the form of the question. Thank you, counsel.
MS. KABBASH: I just want to state --

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MR. AYLSTOCK: I'll give you a standing objection. I'd appreciate you complying with the rules on this.
MS. KABBASH: That's fine. But if you're going to give me a standing objection, then I need to state the basis of the objection that the standards governing disclosures of potential conflicts of interest are beyond the scope of Dr. Wagner's opinions. That's my objection.
Go ahead.
BY MR. AYLSTOCK:
Q. Do you need me to restate it?
A. Yeah, that would help.
Q. Okay. You would agree with me, Doctor, that when designing a study, it's important that the study authors or investigators do not have a financial stake in the outcome of that study?
MS. KABBASH: Objection.
A. It's important that the investigators be honest.
But let's say somebody has a

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great idea and they're inventing the next new great thing, especially in medicine you want to study it and prove it's the next great best thing and you want to present an honest study. But that doesn't mean you wouldn't benefit from being the inventor of the next new great thing. And so technically, based on your question, you could say that person's benefiting, but I wouldn't call them dishonest, or I wouldn't say that that's a bad thing, I guess.
Q. Well, let me give you an example.
A. Okay.
Q. If you're approached as an investigator for a study by a pharmaceutical or medical device company and they say, We want you to do this study, Doctor. We're going to pay for the study. But if it comes out in favor of my particular product, I'm going to pay you an extra $400,000, but if it comes out where it's not in favor of our product or

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it doesn't meet some predefined goal, then we're not going to pay you $400,000.
You would agree with me that you wouldn't do that as a clinical investigator, correct?
MS. KABBASH: Objection to form.
A. I think that goes back to what I was saying in the sense that you have something. You want to test it to see if it's good. If it isn't good, why would you pay somebody for it? If it is good, that person probably deserves some money for coming up with a good idea.
And so, if the person who's doing the testing is the investigator, it's a -- and you're an investor. Why would you give or invest in something that doesn't work or is proven not to work? That doesn't make a lot of sense to me.
Q. So in your world, Doctor, it's perfectly fine to be paid more if the outcome of a study is one way that favors industry but be paid less if it doesn't favor industry? Is that what you're

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testifying to --
MS. KABBASH: Objection mischaracterization.
Q. -- or did I mischaracterize your testimony?
A. I think you mischaracterized it because it doesn't sound good the way you put it. I think it sounds good the way I put it.
Q. Well, I'd like you to answer it the way I put it. So if I could have the court reporter reread the question and you can answer the question that I propose?
(The requested portion of the record was read by the Court Reporter.)
A. I see what I think I object to. It's the "favors industry" part.
I'm not putting industry in this. I'm just saying if there's a good idea and a novel therapy and somebody proves it with a study, that is something that people should rightly be reimbursed for. If they have an idea or thought or a development or a product or a concept that

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doesn't pan out, there is no reason to necessarily pay somebody beyond what the initial investment might have been. And I'm thinking inventors, I'm thinking doctors, I'm thinking industry, I'm thinking of the whole gamut of that I guess is my --
Q. Let's take inventor out of it.
You're just an investigator. You're doing a study for a company that's paying for it.
Should you be paid more if the study comes out one way than if the study comes out the other way?
A. I think an investigator should just be honest.
Q. So there shouldn't be an extra payment one way or the other because that introduces bias, correct?
MS. KABBASH: Objection; beyond the scope of opinions.
THE WITNESS: Do you want me to answer that?
MS. KABBASH: You can answer as

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best you can.
A. I have a tough time applying that in a general way, I guess is the best answer I can give you. I understand the notion of what you're saying, but what we do goes beyond just money. We're not in this for the money. We're in this to help people and I guess that's my objection. If somebody comes up with something that really helps people and if an investigator confirms that in an honest, open peer-reviewed manner, God bless them and make it widely available.
If somebody is behaving in a manner that's falsifies data or hides results or miss -- misleads people, there's no excuse for that, but I --
Q. And they should be held accountable for that, correct?
A. If people -- there are standards that are set by people much smarter in the ethics world than me.
Q. Well, the jury's going to be one of the bodies that will assess that.

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But you would agree if that occurred, the hiding, the obfuscating, the withholding data, that those folks should be held accountable, correct?
A. There are ethical guidelines for all of this. Yes, I don't think people should falsify data, make up data.
Q. Withhold data?
A. It should be an honest --
MS. KABBASH: Objection to form.
A. It should be an honest and forthright presentation of data and studies.
MS. KABBASH: How are you doing? Do you want a break? We've been going about an hour and 20 minutes. Or do you want to keep going?
MR. AYLSTOCK: We can take a break.
(Recess taken from 10:23 a.m. to 10:31 a.m.)
BY MR. AYLSTOCK:
Q. We're back, Doctor, after a quick break.

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Quick follow-up on that medical malpractice lawsuit against you.
Who was the judge in that?
A. I don't remember. I remember his face, but not his name.
Q. Male judge?
A. Male judge.
Q. If you would with me look at Exhibit 5 just real quick, your reliance list.
If you just go to the very first article, it's the author is Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery multicenter study."
I didn't note that article cited in your expert report, correct?
A. It is not.
Q. Did you read that article?
A. I think I have that article in my own files at home.
Q. Okay.
A. I'd have to check to be sure,

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but any -- an article like that from the American Journal on mesh is something I would keep an updated file with at home.
Q. Okay. I take it then you'd consider that article authoritative on the subject?
MS. KABBASH: Objection.
A. I don't consider any single article authoritative.
Q. What about textbooks, do you have any authoritative textbooks?
A. No.
Q. What textbooks do you keep in your office?
A. My office and home I keep the Baggish and Karram textbooks, as well as their surgical atlas, Te Linde's Operative Gynecology, their old atlases, Wheeler's atlas and a few others. I have a couple of surgical books from -- on laparoscopically, Reich's books, Harry Reich's books.
Q. When residents come through your practice, which books do you recommend

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them to review for materials related to the pelvic floor?
A. Actually, I recommend that they review their anatomy more than anything else.
Q. Okay. The next article on that reliance list is what?
A. An article in the British Journal OB-GYN 2010 "Inside out versus outside in obturator tapes."
Q. Did you read that article?
A. I don't think I recall reading that article specifically beyond anything that might be in the abstract?
Q. So, as we sit here today, do you know if anything in that article supports or contradicts your opinions in your expert report?
A. Again, my expert report is a summary of my opinions, and my opinions are based on a lot. They're based on my training, they're based on my experience, they're based on my review of the literature, and there are parts of

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literature that contradict or don't contradict each other sometimes. It's based in part on my interaction with other doctors either at my hospital, at various national meetings. My opinions are in the report, but they're my opinions based on the totality of my medical training and experience.
Q. So as we sit here today, you're not in a position to testify under oath that you've reviewed each and every item on your reliance or supplemental reliance list, correct?
A. I haven't reviewed every -- I have not read every single word of every article, no.
Q. In fact, there are probably articles on there you haven't reviewed at all, correct?
A. No, I think actually there are. Counsel was good at providing me with articles that I found very -- very nicely augmented my own personal collection of data.

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So, I don't have the same access to the same infrastructure that clearly counsel has to do literature reviews. So I tend to rely on reading articles, studying the bibliography, requesting more articles. It's sort of old-fashioned the way I do it.

Q. Did you do your own Pub Med search in preparation of your report or rely on what was provided to you by counsel?

A. I did not do a Pub Med search. I tend to have files at home that I keep and I supplement and update and go through periodically. Some of it matched up. I think I had out of the reports in my expert report, half of them I already -- were in my library.

Q. Now, toward the back of that document there's deposition transcripts.

Have you read any depositions of internal Ethicon personnel?

A. Yes.

Q. Okay. Which ones did you read?

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A. I read a couple of depositions. They must be in here somewhere, but I read depositions on a Dr. Elliot. I read depositions on Dr. Rosenzweig. I read depositions from Piet Hinoul. I read depositions on a gentleman named Weissberg. Weissberg, yeah, Martin Weissberg. His name's right here (indicating). And --

Q. What about Dan Smith, did you read his deposition?

A. I may have. I don't specifically recall it.

Q. Were you given the entire deposition or excerpts of depositions?

A. In the cases of Elliot and Rosenzweig, I have their entire depositions, general depositions, as well as case specific depositions I've read.

In the cases of Piet Hinoul and Martin Weissberg, I have partial transcripts that I read. I think they were direct transcripts -- no, actually, that's not true. One of them also had

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their own counsel questioning them too. In fact, it was Maha who was questioning them.

Q. So, with regard Dr. Elliot and Dr. Rosenzweig you know are not Ethicon personnel, they're --

A. I do know that, yes.

Q. They're urogynecologists, correct?

A. Yeah, I believe they are experts for the plaintiffs.

Q. And the other witnesses you identified are internal Ethicon personnel, correct?

A. Yes. I believe they're medical doctors.

Q. Okay. And you were given not their entire depositions, but excerpts; is that correct?

A. Yes, although I have to say that there are flash drives I haven't completely reviewed that might have their whole depositions.

So, the question was was I given

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it? I may have been given it, but I haven't reviewed it.

Q. But what you reviewed were the excerpts provided to you by counsel --

A. Yes.

Q. -- for Ethicon, correct?

A. Yes.

MR. AYLSTOCK: I take it on the flash drive are the excerpts, not the entire depositions, Ms. Kabbash?

MS. KABBASH: I don't know the answer to that question. It may be the case.

MR. AYLSTOCK: Okay. If not, I'd request the excerpts that were provided to Dr. Wagner to review be given to me, please.

BY MR. AYLSTOCK:

Q. Were they highlighted or comments made on those excerpts, or just excerpts?

A. No, they were just trial testimony, no highlights and no comments.

Q. Your time reviewing all of those

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materials is reflected in Exhibit 3, correct?
A. No. Most of the time we just talked about I reviewed recently.
Q. So that would be in either the invoice that I wasn't provided yet or the e-mail or would be reflected in a future invoice?
A. Or the invoice that I haven't provided her with yet.
Q. Right, okay.
MR. AYLSTOCK: Let me hand you Exhibit 9.
(Exhibit Wagner 9, Gynecare TVT Instructions for Use, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. Do you recognize Exhibit 9, Doctor?
A. I do.
Q. You recognize that as the instructions for use for the TVT Retropubic product, correct?
A. Yes.

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Q. In your report, you state that you use the instructions for use for educational purposes with your residents, correct?
A. I do.
Q. Why is that?
A. It goes to sort of what you asked me about textbooks. The surgery that we do now is so different than the surgery when I was trained. When I was trained, the operations we were doing had been pretty much unchanged for 80 to a hundred years, and we had atlases and textbooks that reflected those operations. I mean, our suture materials were better. Our operating environments were better. Our surgical techniques were better, but our actual procedures were pretty much unchanged. And in today's world, whether it's vaginal slings, vaginal mesh repairs, whether it's single incision surgery, whether it's robotic surgery, it's really hard to find an up-to-date textbook to describe these things. And by the time

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you do, it's probably outdated within a couple years.
So, I just found that when I have a new resident or fellow and they have not seen this operation before or they've not handled a particular device before, a stapler, a single incision, I encourage them to take this with them and look at it.
Q. I think you even say you encourage them to take it home and study it, correct?
A. Yes, I do.
Q. And that's because what's in the IFU should be the most up-to-date information known to the company as to the implantation procedure and how to perform it, correct?
A. Again, I have problems with that term "up-to-date."
You know, I think that the IFU reflects the company's obligation to describe their product and to describe adverse potential side effects related to

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their product. And yes, I mean, you could learn something tomorrow and it might take an IFU a while to catch up.
I don't expect the IFUs to replace surgical judgment or up-to-date surgical management, but I do find it's a very good way to introduce somebody to a product, and that's really what I would use them for. Whether it's TVT or really any other product, to introduce a resident to that product.
And I might say to them look, it says here that you can X, Y or Z, but we found you could even do A, B and C with this too and expand on it. Or I might say it says here you can do this, but some of the recent data says you can't do that.
So again, it's a good stepping stone to get off on teaching somebody how to use a product, is how I would use the IFU.
Q. And you mentioned adverse events are reflected in the IFU, correct?
A. Yes, they are.

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Q. And warning and precautions and contraindications, correct?
A. Yes.
Q. And you find and tell your residents it's important that they review those materials as well as the implantation procedure to come to an understanding as to what might result from the implantation of this product, correct?
A. Correct.
Q. Now, if we look at this IFU, and I'm referring now to the --
A. The writing is so small.
Q. I know. It's how it was given to me. We can probably get a magnifying glass if we need.
But, as far as the warnings or adverse events reflected in this IFU, it talks about mesh extrusion, exposure and erosion into the vagina, correct?
A. Yes, under the "adverse," because you said "warnings," but that's a separate section.
So you were referring to the

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"Adverse Reaction" section?
Q. Yes.
A. Yes, it says bullet 4 says that.
Q. And you would agree with me that that is an event that can be caused from the TVT device, the kit, correct?
A. A mesh extrusion or exposure or erosion is really an adverse reaction that's common to all mesh procedures.
Q. Okay. And so, specific to the TVT Retropubic, you would agree that it has the capacity to cause those adverse reactions, correct?
A. Correct.
Q. And it has the capacity to cause those adverse reactions even in the absence of doctor error, correct?
A. Correct.
Q. And another adverse reaction listed here is acute and/or chronic pain.
You see that, correct?
A. Yes, I do.
Q. And again, the TVT Retropubic has the capacity to cause that in certain

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women even in the absence of doctor error, correct?
MS. KABBASH: Objection to form.
A. Yes.
Q. And it also says voiding dysfunction.
You see that, correct?
A. Yes.
Q. Again the TVT devices have the capacity to cause voiding dysfunction in women even in the absence of doctor error, correct?
A. Correct.
Q. Pain with intercourse in which some patients may not resolve.
Do you see that?
A. Yes, I do.
Q. You would agree that pain with intercourse in some patients may not resolve following implantation of the TVT devices, correct?
A. Correct.
Q. And that can occur even in the absence of doctor error, correct?

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A. Correct.
(Phone rings.)
MR. AYLSTOCK: Do you need to get that, Doctor? If you do, it's fine.
MS. KABBASH: If you do, it's okay.
THE WITNESS: Can I take like a one minute break?
(Recess taken from 10:47 a.m. to 10:51 a.m.)
MR. AYLSTOCK: Where were we?
(The requested portion of the record was read by the Court Reporter.)
BY MR. AYLSTOCK:
Q. Now, with regard to the TVT products, you would agree with me, Doctor, that implantation of those products can result in neuromuscular problems including acute and/or chronic pain in the groin, leg, thigh, pelvic and/or abdominal region, correct?
A. Correct.
Q. And those can be caused by the

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TVT products even in the absence of doctor error, correct?
A. Yes.
Q. Same question with regard to recurrence of incontinence, correct?
A. Correct.
Q. And same with regard to bleeding, including hemorrhage or hematoma, correct?
A. Correct.
Q. And you would also agree that following the implantation of the TVT family of products, one or more revision or surgeries may be necessary to treat these adverse reactions, correct?
A. Correct.
Q. And that can occur even in the absence of doctor error, correct?
A. Correct.
Q. And you would agree that the TVT mesh -- well, you're aware, Doctor, are you not, that in the TVT family of products they're all the same polypropylene mesh, correct?

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A. Correct.
Q. And that's Prolene mesh, correct?
A. Correct.
Q. Do you agree that in some cases, that Prolene mesh needs to be removed in whole or in part and significant dissection may be required of the tissue to get to the mesh, correct?
A. Correct.
Q. And that can occur with the TVT products even in the absence of doctor error, correct?
A. Correct.
Q. Have you personally explanted Prolene mesh in your practice?
A. Yes.
Q. How many times?
A. I've explanted Prolene mesh in suburethral slings probably four or five times, but I've explanted mesh in other parts of the vagina in the operating room maybe 20 to 30 times and in the office multiple times.

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Q. Prolene mesh, correct?
A. Prolene mesh like you'd see with the Prolift system. Typically that was my main product, so it would be primarily the Prolene mesh in the Prolift system.
Q. Okay. Where a patient presents with the need for explantation of the mesh, is that something you normally do personally, or do you refer cases out for treatment sometimes?
A. No, I actually do that personally.
I guess I should tell you too that of the TVTs that I have treated, I think only one of them was mine. The rest -- actually, two of them were mine. The rest were referred to me. So about half of the four or five were referred to me. The other two were mine.
Q. And by "mine" you mean --
A. My patient.
Q. -- you implanted the original TVT device, correct?
A. Yes, I implanted the original

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TVT device.
And I should say that on one of them it's pretty clear that the patient disrupted the repair 'cause she had sex the next night and disrupted the repair, so I don't think that was the fault of anything other than the patient not adhering to her restrictions.
Q. In the other case, did the patient adhere to the instructions and refrain from sex for the appropriate time?
A. As best as I know, yes.
Q. And she still had suffered an adverse event from the TVT product?
A. She did. She had a small mesh erosion that I had to excise.
Q. And that mesh erosion, I take it, was not caused by your error, correct?
A. Error's a funny word. We do our best to section, we place it where we like to place it. We keep our fingers crossed that we haven't devitalized the tissue so that it heals well, but it can occur without any doctor error. It's an

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inherent part of any mesh procedure is the risk for mesh erosion.
Q. And in that particular case, you have no reason to think that you placed it improperly, correct?
A. I like to think I did a good job.
Q. I'm not here to disagree with you.
And yet she still suffered an adverse outcome, correct?
A. Correct.
Q. Did you report that to the company?
A. No.
Q. Did you report it to the FDA?
A. No.
Q. Why not?
A. It happened about four years ago, and maybe I wasn't as conscious back then of these types of events being reported. I think that's more of a modern concept.
But I also think in general when

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we deal with mesh erosions, it's one of those things we go into our surgery counseling patients about knowing that it can happen, knowing that occasionally we have to revise it a little bit either in the office or afterwards to make things perfect. So, I'm not even sure that in today's world I would report it.
Q. Okay. Have you ever had occasion to remove an entire TVT sling?
A. Twice.
Q. Were those under general anesthesia, I take it?
A. Yes, they were.
Q. Did those involve surgeries?
A. Did they involve surgeries, is that the question?
Q. Were they complicated surgeries?
MS. KABBASH: Objection to form.
You can answer.
A. I don't think explanting the mesh is terribly complicated. It's a pretty simple proposition in the sense of you're finding the mesh, dissecting it

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out, carrying it out as far as you can laterally and excising it. It's not brain surgery. But it tends to be mesh that's been there for a while. It's surrounded by normal scar tissue. There's no tissue planes in that region, so it makes the dissection tedious. I would describe it as tedious, not difficult.
Q. Okay. And tedious in that the mesh can be encapsulated in that scar tissue, correct?
MS. KABBASH: Objection to form.
A. Well, you want the mesh to have a scar tissue that fills it in.
It's like a -- it's like -- it's like before they pour cement they've got metal rods that sit there and they pour the cement in there. You want the scar tissue to be the cement that fills in around the mesh. So you're trying to dissect out the metal rods like a big piece of concrete. But the concrete's like normal scar, that's what you're looking for.

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Q. So it's tedious to get that mesh out of the scar tissue --
A. Yes.
Q. -- or concrete, is what you're saying?
A. Yes, it's tedious.
Q. Certainly more difficult taking it out than putting it in; you'd agree with that?
A. I would agree with that.
Q. So, other things that you agree could be caused by the TVT family of products even in the absence of doctor error would include seroma, correct?
A. Yes.
Q. Urge incontinence, correct?
A. Yes.
Q. Urinary frequency, correct?
A. Yes.
Q. Urinary retention?
A. Yes.
Q. Adhesion formation?
A. It's listed here. I guess yes, I would agree I guess that's possible.

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I'm not sure where the adhesions would be though.
Q. Okay. Atypical vaginal discharge?
A. Yes.
Q. You would also agree that exposed mesh from the TVT product can cause pain or discomfort to the patient's partner during intercourse, correct?
A. Yes.
Q. And death is also a potential adverse reaction, correct?
A. Yeah, it's listed here, but I think that's an anesthetic reaction, not a TVT adverse reaction.
Q. You would agree though that all of those things can be caused following --
MR. AYLSTOCK: Strike that.
Q. You would agree that all of the aforementioned items can be caused from the implantation of the TVT family of devices even in the absence of doctor error, correct?
A. I think a lot of these things,

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as I look at them here, are related to just any surgery to fix incontinence, but I would agree that any of these are possible with implanting TVT. I guess if you assume an anesthetic reaction, even death is possible. So I'll say yes, if you're in the operating room putting in a TVT, any of these things could happen.
Q. Even in the absence of doctor error?
A. Even in the absence of doctor error.
Q. Now, if we go to page 3 of your report, Doctor, you talk a little bit about the TVT IFU. And I think you would agree with me that the IFU should be providing the best description of the current products, its use and its complications and warnings, correct?
A. I think that if you're referring to my expert report, I'm talking there about sort of what I said before about giving a resident or a fellow a piece of material that they can go home and

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introduce themselves to that will give them that landscape of what this is all about.
Q. What you write on page 3 is that you find that the IFU, and in this case the TVT family of products IFUs, provide the best description of the current product, its use, potential complications, and warnings, correct?
A. Yes. And I would go back to -- actually, I would go back to the sentence before that. I say as part of my resident education, I guess I should say fellow education, that's the context in which I would make that statement. It was probably monographs and potentially -- and disks and who knows what that is better description, but in terms of having something that's right there that you can teach people with, the IFU is something I've used for years. In that setting, yeah, I think it provides me the best information.
Q. Okay. And that's what you teach

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your residents, correct?
A. Yes.
Q. With regard to the instructions for use, have you ever designed any instructions for use?
A. No.
Q. Have you ever held yourself out as an expert in what should or should not be in instructions for use?
A. No.
Q. Are you familiar with what the or have you ever studied what the industry standards are with regard to what should or should not be in the instructions for use?
A. No, I have to say I'm not aware of the industry criteria for that.
Q. So you're not holding yourself out as an expert as to what should or should not be in instructions for use, correct?
MS. KABBASH: Objection to form.
A. I would hold myself out as an expert in teaching residents.

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Q. Okay.
A. And I think that as part of that, you need an armorterium [sic], is that the word I'm looking for, of tools.
Q. And one of the tools is the IFU?
A. Is an IFU.
Q. Okay.
A. So I would hold myself out as an expert at teaching in that regard.
Q. Okay. But not with regard to --
A. But not --
Q. -- IFUs specifically, correct?
MS. KABBASH: Objection to form.
A. But not with the industry standards for what goes into the IFUs.
Q. Correct.
Is that correct?
A. Correct.
Q. Okay, thank you.
Now, the instructions for use on the TVT products also have implantation instructions for the physician, correct?
A. Yes.
Q. And similarly, would you agree

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that with regard to the manner of implantations, it's important that the physicians be told through the IFU the correct manner of implantation of the particular product?
A. I think how a physician learns to do this should not be just by reading the IFU and doing this. I think that if somebody wants to expand their surgical repertoire to anything, they should go to postgraduate courses, be proctored, they should learn -- if I'm understanding the question, the question is can a surgeon just read the IFU and do the surgery, I would say no.
Q. Yeah, that really wasn't my question.
I guess my question relates back to in your report on page 3, you would agree that the IFU should be where the physician -- one of the things that the physician relies upon to look for the correct manner of implantation of the product, correct?

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A. I think the IFUs provide a nice written summary of standard use of the product.
Q. And because of that, because doctors rely on it, it's important that the IFUs be accurate, correct?
A. I think the IFUs should be accurate, yes.
Q. Because if the IFU's not accurate, a doctor may rely on it and give bad information to a patient or implant it incorrectly or do something else that's wrong, correct?
A. A doctor could implant something incorrectly for a variety of reasons that probably have nothing to do with the IFU.
Q. Well, you agree if the IFU is incorrect to the best manner of implantation, or unclear, that can lead to adverse consequences to the patient, correct?
MS. KABBASH: Objection to form.
A. I would like the IFU to be as clear as possible.

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Do I expect it to be a perfect document? No more than I expect, necessarily, my textbook chapter to be a perfect document. But in general, they're a good summary of whatever product it is and what the company feels should be part of its use and reactions and warnings and side effects.
Q. Okay. Let's go now to your expert report, Exhibit 6.
Did you write this report?
A. I think that probably two-thirds of this are my dictation and corrections of my dictations. Clearly these reflect my opinions, but in terms of organizing this, I clearly had help from counsel. They helped me organize sections. But most of this is dictated by me and corrected by me.
Q. You said about two-thirds?
A. About two-thirds is directly from my Dictaphone. The others are paragraphs that I had editorial control over and changed in certain ways, but

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probably the scaffolding came from counsel. But I approved everything that was in here and these opinions are mine.
Q. Okay. But as far as the text in the report, about one-third was from counsel and --
A. At least the initial scaffolding came from counsel.
Q. Okay. Did you review reports from any other of Ethicon's experts? Ethicon's experts.
A. Did I review reports, I'm not sure I understand, is that a general question, like if I've seen any reports from Ethicon at all? Is that what the question is?
Q. No. You understand you're not the only expert hired by Ethicon Johnson & Johnson to defend them in these lawsuits, correct?
A. I assume that, yes.
Q. And have you reviewed reports from other of Ethicon's experts in preparation of your report?

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A. No, I don't think I have. No, I have not.
Q. Have you authored any other previous expert reports for any mesh devices?
A. No.
Q. Have you ever been an expert witness before this case?
A. Yes.
Q. In what context?
A. In malpractice context.
Q. Was it involving a mesh product?
A. No.
Q. Were you involved with -- were you hired by the defendant's lawyer in that case?
A. No. I was hired by the plaintiff's lawyer.
Q. What was the nature of that case?
A. The nature was a patient of mine who had gone to get a second opinion from another physician. She had post-hysterectomy vaginal vault prolapse

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and was seeking a surgical repair. This was about 14 years ago. And I recommended she have a vaginal suspension, like a sacrospinous fixation. The second opinion from the doctor in the city agreed, but she also was requesting just removal of her ovaries for sort of like no reason, and I didn't think that that should be done.
So, this other doctor agreed to laparoscopically remove her ovaries. She had bad adhesions. When he looked inside, the ovaries looked normal, but they were all bound down. And in taking out the ovaries, he injured the bladder. In repairing the bladder, he denervated the bladder so that she was left with basically very bad incontinence from intrinsic sphincter deficiency. Afterwards she had to fly out to California. Shlomo Raz put in a sling. She ended up having a long, complicated postoperative course. And my opinion at the time was that the removal of the

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ovaries was unindicated, particularly when looking inside suggested that it would be a very complicated procedure in what otherwise was supposed to be elective.
Q. So you were her treating physician initially?
A. Her initial treating physician was my senior partner, and she was referred to me for a consultation interoffice when she developed post-hysterectomy vault prolapse.
Q. Do you know Shlomo Raz personally?
A. I do not.
Q. And you recommended that she had a pelvic repair without the use of mesh, correct?
A. We were not using mesh for those repairs at that time vaginally. We were using mesh via laparotomy to do sacrocolpopexies, but I felt that her defect was primarily isolated to the apex and she would do very well with the sacrospinous fixation.

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Q. Turn with me to page 2 of your report.
Since that case went back a couple of decades, or I think you said 14 years.
A. Actually, I know 'cause I missed my son's -- oldest son's high school senior prom party because I was testifying and I got stuck in traffic coming home. So I know he had to be 18 and he's 32 now. So it had to be 14 years ago.
MR. AYLSTOCK: I think Ms. Kabbash and I can relate.
MS. KABBASH: Yes, unfortunately we can.
BY MR. AYLSTOCK:
Q. So, in your report, you set forth for the past 25 years you've been in the same private practice, correct?
A. Yes.
Q. And your primary focus is surgical gynecology for benign conditions, correct?
A. Correct.

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Q. And that's been your primary focus for the past 25 years, correct?
A. Yes.
Q. And you would agree with me that stress urinary incontinence is generally considered a benign condition, correct?
A. Correct.
Q. On the next page you discuss your experience with the Burch procedure, correct?
A. Correct.
Q. And did you generally have good experience after performing the Burch procedure to treat stress urinary incontinence on your patients?
A. I think I had typical Burch outcomes.
Q. And do you know what your failure rate was following the Burch procedure for SUI?
A. I've actually never followed any of my patients for their failure rates prospectively. But my experience with the Burch at the time, I mean, my counseling

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for the patient at the time was we're going to spend three to five days in the hospital. You're going to have a catheter for five to seven days, and you could have some prolonged bladder dysfunction, and there is a fairly good chance we will cure you, 70 to 80 percent cure rate, and about a 50/50 lifetime cure rate. Those were the statistics that I remember quoting the patients back them.
Q. With regard to the Burch procedures, you would tell your patient you could expect about a 70 to 80 percent cure rate?
A. 80 percent cure rate.
Q. And with regard to adverse reactions with regard to the Burch procedure, what would you tell your patients?
A. That it was abdominal surgery. Although that it was outside the abdomen, it required a C-section incision and the risk of that would be related to bleeding, infection and poor healing. There's a

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risk of bladder injury. There's a risk of urethral injury. There's a risk of failure. There's a risk of recurrence. There's a risk of under-tightening or overtightening, and then there's the associated risks that go with any vaginal surgery. You could have vaginal scarring, strictures, pain. A lot of things are listed in the IFU that we just went through are symptoms of any vaginal procedure.
Q. What was your experience though in your patients with the Burch procedure? Did you have patients that experienced chronic pain following your performing a Burch procedure?
A. But the number had to be low, certainly under 10 percent. Chronic pain is one of those things that you can see almost any procedure, but it's not a common side effect of any real procedure. It's always just out there as a possibility.
Q. So, generally speaking, with

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regard to the Burch procedure, your patients did well, did not suffer an adverse event, correct?
A. They had typical --
MS. KABBASH: Objection.
A. -- Burch outcomes. You know, there were times when it didn't work well. There were times when they had catheters for three or four weeks. There were times when it didn't tighten them enough.
You know, with the Burch it was funny because you didn't have different types of options. It was one procedure. So if somebody had intrinsic sphincter deficiency, we would try to do a really tight Burch. If they just had hypermobility, we wouldn't do a really tight Burch. There was a lot more guesswork with Burches, and there was a lot more involved in recovery and pain and complications.
Q. As far as long-term complications from the Burch other than those individuals who suffered from a

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recurrence, did you have particular patients that had long-term consequences following the Burch that you can recall?
A. No, but I know I had patients who needed a pubovaginal sling because their incontinence wasn't better. I recall hematomas. We were always worried about bleeding.
Q. Those would be transient conditions, correct?
A. Well, transient for months. Yeah, they didn't -- if they had a Burch when they were 60, they didn't have those conditions when they were 80, but they may linger for a long time.
One thing to also remember about a Burch is that if you did have a hysterectomy, the vessels in that retropubic space were often huge too. So there was a significant risk of bleeding with a dissection. It was a much more invasive operation.
Q. One of the risks that's not associated with the Burch, however, is

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erosion or extrusion, correct?
A. That is correct.
Q. That's a risk that's unique to the TVT family of products or other mesh involved in SUI?
A. It's absolutely unique to operations other than the Burch. The pubovaginal slings, synthetic material could erode. The Burch did not have erosions.
Q. If we turn to page 4 of your report, you detail your experience with the TVT products. I'm going to focus on the TVT Retropubic product for now.
It looks like you performed about 600 to 800 procedures with the device?
A. Yeah, that's my best recollection. We started doing them around 2000, and it became virtually standard. We used it for every patient. That was really the only device on the market for a while that we used.
Q. I'm not going to mark it because

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I want to take it back, but I'm handing you a TVT device box.
Do you recognize that?
A. I do. It brings back memories.
Q. All right. So, one of the memories it brings back is that the TVT has the polypropylene mesh, the Prolene mesh we discussed, and it's actually fixed to the instruments, correct?
A. It is, yes.
Q. So the device is not just the mesh, it's the instrumentation and the instructions for use, correct?
A. Yes. And I think the handles were reusable. They were separate.
Q. Okay. But the actual trocars here attached?
A. Yes, they were attached and the handles, if I recall, screwed into the bottom of the metal trocars.
Q. So the trocars weren't reusable, just the handles, correct?
A. Just the handles, yes.
Q. How much were you paid,

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approximately, for TVT Retropubic surgery? Do you remember what your billing rate was?
A. We don't get paid a lot for doing gynecologic surgery.
Q. What's not a lot?
A. Let me put it this way. There's most gynecologists over the last 15 years, at least in this area, about 70, 80 percent of them have given up doing gynecologic surgery for reimbursement reasons, or they're not skilled in minimally invasive approaches, but the reimbursements for gynecologic surgery are not that great. And I'm sure my office manager could give you a better idea what we're reimbursed.
But if people were making a lot of money pulling out TVT, then they wouldn't be sending their patients to me to have them done. They could apparently make more money in the office seeing patients for annual visits than they can taking them to the operating room, so.

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Q. So, how long did it take you to implant a TVT device?
A. Fifteen, 20 minutes.
Q. With regard to the billing rate, was it a thousand dollars?
A. It didn't matter what we billed. We're HMOs.
Q. So reimbursement rate?
A. I could bill a million dollars and they'll pay me 500.
Q. Well, what's your best estimate as far as the reimbursement rate for the TVT?
A. It's never been a lot. If I had to guess, it's really a guess, it's certainly under 2,000. It could be under 1500. It could be some insurance plans where it's only 500. It would vary from insurance plan to insurance plan.
We are a managed care dominated environment. So we can't set our fees. We basically take whatever they pay us.
Q. Somewhere between 500 and $2500?
A. If I got $2500 regularly to do

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the TVT, I think I'd be on my sailboat right now.
Q. But that's a fair estimation --
A. That would be the most I ever got, I think.
Q. So, you were also referred patients to implant the TVT --
A. Yes.
Q. -- products, correct?
A. For at least 15, 20 years, probably the majority of patients I operated on have been referred to me, yes.
Q. Do you have an operating suite in your office?
A. No.
Q. So where did you perform the operations?
A. In the operating room.
Q. At the hospital?
A. Yes.
Q. Just one of the two hospitals you had privileges in?
A. Actually, I only had privileges at Huntington until very recently. I

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added privileges at Winthrop I think in 2012 or '13, '14, very recently.
Q. I'm not going to ask you questions about these other products yet. I'll save that for later.
But you also detail other Ethicon SUI products you used over the years, correct?
A. Correct.
Q. And what you say in your report is that it looks like after 2006, you started using another Ethicon sling; is that right?
A. I did.
Q. Why did you switch from the TVT Retropubic to another sling?
A. I found that it was a less invasive operation, and I had very good success with it.
Q. Did you find that you had better success with the next Ethicon device than the TVT Retropubic?
A. I had a better success setting that tension exactly the way I wanted to

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with that device.
Q. So did you completely transition from the Retropubic to the TVT Secur at that time?
A. Almost completely.
Q. And because you had found it to be a better product for you, correct?
MS. KABBASH: Objection to form. Go ahead.
A. I found that that product worked very well for me and had advantages in terms of less pain and pretty much eliminated the risk of bladder injury and retropubic hematoma in my hands.
Q. So, one of the reasons you stopped using the TVT Retropubic is because you found a successor device had less risk, correct?
MS. KABBASH: Objection to form.
A. I found that I could use that TVT device, the one that replaced the retropubic, and get very good success rates with it with less pain and fewer complications.

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Q. So you found the success rate to be better for your patients, correct?
I'm sorry. You found the successor product to the TVT Retropubic to result in less complications for your patients, correct?
A. In my hands, I felt that way, yes.
Q. And then currently, do you use the TVT Retropubic device at all?
A. Yes.
Q. When do you use it?
A. Primarily when somebody has stress incontinence with a minimal hypermobility or urodynamically proven intrinsic sphincter deficiency or when they failed a prior transobturator sling almost regardless of what I find on physical exam or urodynamic studies.
Q. Let me make sure I was clear in my question because you do talk about the TVT-Exact being your sling of choice for the intrinsic sphincter deficiency, correct?

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A. Correct.
Q. In your prior answer, were you talking about the TVT-Exact or original TVT Retropubic device that I have with me?
A. I apologize. I miss -- I misunderstood your question.
I don't use the original Retropubic at all. That's why I kind of enjoyed seeing that.
Q. When is the last time you saw a box like this, the TVT Retropubic?
A. I haven't seen that box in years.
Q. And that's because you don't use it anymore, right?
A. I don't use it. I use the Exact when I want a retropubic approach.
Q. And that's because you find that with the Exact, your patients have less complications, correct?
MS. KABBASH: Objection to form; lack of foundation.
A. I think the big advantage for me for the Exact one is the metal guides here

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are very firm and the Exact is a smaller trocar, or guide, and it's also more of a flexible guide. So I can feel my way up the back of the pubic bone and through the retropubic space more readily than I could with the original TVT. To me there's more of a tactile feedback that I get with the Exact.
Also, there's one other advantage of the Exact is that you could place the trocars and they have a plastic sheathe and you can leave the sheathe in place and do one cystoscopy, which made it easy to do.
Q. So, in your experience, the TVT-Exact, because of those advantages, results in less complications for the patient, correct?
MS. KABBASH: Objection.
A. It makes a little quicker to do the procedure because it only involves one cystoscopy and I feel more confident in when -- in how I place it. I'm not aware of any literature or study that compares

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exactly the original Retropubic that shows any lower complication rate.
Q. But in your experience, you prefer the Exact because you find it to be a superior device than the original Retropubic, correct?
MS. KABBASH: Objection; asked and answered.
You can answer.
A. In my hands, the way I feel my way through the pelvis, I'm more confident placing the Exact. That's my -- that's my best answer.
I don't have any peer-reviewed objective data to tell you that it's better. I feel that I have a better feel for where I'm guiding the trocars with the Exact than I did with the original TVT.
Q. So to you, you feel it's a superior device?
MS. KABBASH: Objection.
BY MR. AYLSTOCK:
Q. The Exact.
A. I just come back to in my hands,

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when I'm doing it, I feel more confident doing it.
Q. Okay. When is the last time you did an original TVT Retropubic implantation, 2006?
A. No. I think I did one or two recently when I was at a hospital, I can't remember which hospital it was, and all the TVT-Exacts had expired. And so I asked them if I could have the original device and they gave it to me.
Q. Okay.
A. But I haven't seen that package in a long time because they gave it to me unwrapped and everything.
Q. But absent an expiration on the Exact, you don't use the TVT Retropubic device anymore?
A. That's correct.
Q. When you were using the TVT Retropubic device, did you use mechanical-cut or laser-cut, or do you know?
A. I am pretty confident that when

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I used that, it was virtually all mechanical-cut. I don't recall being familiar with the concept of laser-cut until I used the TVT Secur. So I'm fairly confident that everything I used was mechanical-cut.
Q. Did your sales rep or anybody from Ethicon ever explain to you what the difference was?
A. Not that I recall.
Q. Do you know why Ethicon switched to also creating a laser-cut TVT Retropubic device?
MS. KABBASH: Objection to form.
A. I don't know why.
Q. Did you ever ask them?
A. No, I don't think I ever have. I may have asked my rep when I had the TVT Secur questions about the laser-cut, but until recently, maybe four or five months ago, I actually wasn't aware that you could get the meshes in both ways. That was a relatively new discovery on my part. I think I've always used the

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mechanical-cut except for the Secur because I think the Secur only came laser-cut.
Q. When you did become aware of the difference, what were you told about why there was a difference?
A. I recall, I think, having that discussion with my GYN clinician in the O.R., possibly when they were reordering, and I remember thinking it didn't make any difference to me. I think I remember saying whatever's cheapest, if there was a difference.
Q. Okay. If you add up all of these Ethicon devices over the years, it looks like you've done 2,000, 2400 such operations involving the TVT family of products.
Is that about right?
A. I think that's probably about right.
Q. Did you ever keep a registry for your patients, given the large number that you did?

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A. No. I think that's my -- if I had more time, I would do a lot more, but, you know, I have a large surgical volume and just taking care of people is pretty much -- I'm pretty tired at the end of the day.
Q. But you've considered it?
A. I would love to have maybe an institutional affiliation where I could have a research manager who could collate data for me and things, but in private practice, it becomes very difficult.
Q. Did you ever ask your Ethicon sales rep for anybody at Ethicon to help you out with funding or personnel to do such a registry?
A. No. But now that you bring it up, I kind of wish I had.
Q. I do too.
A. I kind of wish I had.
Q. Did you ever do any sort of surveys, mail-outs or anything with regard to complication rates with your patients?
A. Once, a partial, and we

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abandoned it. It was a project for one of my residents regarding using the apilitis [ph] for single site surgery and the risk of hernias afterwards. We were trying to do a follow-up study on hernias, so it had nothing to do with this type of thing.
Q. And I take it, like many physicians, the women you treat come and go in your practice?
MS. KABBASH: Objection to form.
A. Roughly half of the people that I operate on, probably fewer now, but over the last 20 years, half the people I operate on are my patients. The other half are referred and I send them back when I'm done.
Q. Okay. So, with regard to complications or things that may happen, you wouldn't be in a position necessarily to know unless they specifically came back to you, correct?
A. I would know about mesh complications because they would all rebound back to me.

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Q. Who would?
A. The referring doctor. I mean, if there's a mesh erosion on a Prolift or something that they see on an annual visit, they're going to send that patient back to me, almost certainly. Or the patient themself is going to come back to me.
Q. There may be situations where those patients move away?
A. Absolutely.
Q. And they might not even see the doctor who sent them to you?
A. That's correct.
Q. With regard to complication rates for those patients that are lost to follow-up, you wouldn't have any way to know?
A. No, but it's probably balanced by the patients who moved to Long Island, had their surgery elsewhere and somebody sees an erosion and sends them to me.
Q. So you get those too?
A. I get those too.

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Q. How many of those have you done?
A. I think that was the total I was giving you before. I think probably in the operating room mesh excision for Prolift, maybe 20 to 30 times, and for the slings I think four or five times is all.
Q. Okay.
A. Those are my best guesses though.
Q. When you started using the TVT Retropubic device, I take it you reviewed the instructions for use prior to implantation, as you would teach your residents to do?
A. I'm sure that I did. Although I probably didn't start teaching residents 'til 2004 or so. But yes, I'm sure that I did.
I was familiar with the IFUs, and I tended to look at them myself.
Q. Did you familiarize yourself with the clinical data that supported the TVT Retropubic device?
A. Yes.

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Q. Was it important to you when you were putting in this device that there be clinical data?
A. Yes.
Q. Why is that?
A. On a general perspective, I'd like clinical data on anything that I'd put in a patient. But there are certainly urogynecologic procedures for incontinence that seem great and then the long-term data wasn't as good. The needle suspension procedures, like Pereyra's and Stamey's, would seem to be great and then patients would quickly fail. So, historically, we had had issues with procedures that seemed to work and then didn't work as well.
The other example would be the anterior repair and Kelly plication.
So, a lot of our urogynecologic procedures up to the TVT didn't have a great long-term track record, or even a great short-term track record for that matter.

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Q. So, in your experience, clinical data and having that clinical data prior to bringing a product to market is important to urogynecologic experts --
MR. AYLSTOCK: Let me rephrase that. Strike that.
Q. In your experience, in speaking with other urogynecologists and gynecologists, clinical data is important to them when looking at whether a new product should be used for the treatment of stress urinary incontinence, correct?
A. Yeah, I'd like to know what clinical studies have been performed and what their outcomes were and what the follow-up was and the quality of the data. It's all in -- it's a process of evaluation.
Q. If you had a product with no clinical data behind it and it was an experimental product basically, would you try it on the patient without telling the patient that there was no clinical data to support it at this point?

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MS. KABBASH: Objection to form.
A. Well, I don't think I get that past my hospital review committees or anything like that. I don't think it's a question of -- I mean, I would not want to do that, but I don't think I could get it past my hospital ethics committee or anything, rightly so.
Q. That's because with regard to products without credible clinical research, those should be performed in an experimental setting, not in a clinical setting with patients?
MS. KABBASH: Objection to form.
BY MR. AYLSTOCK:
Q. Correct?
A. Yeah.
You know what it reminds me of is like the gentleman who invented the coronary bypass, and they brought him before Congress because he was working on dogs and he presented his series. He said, My first series was 12 patients and they all died. He goes, My second series

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was 12 patients and six of them survived. And he said, My third series was 12 patients and they all survived. And he said the first two series were with dogs, the third series were with humans.
So I think that you want to do some type of testing, whether it's animal testing, whether it's product testing, efficacy testing, before you put something in people.
Q. But with regard to bringing a product to market and selling it to surgeons across this country, do you believe it's important that there be clinical data to support the product?
A. You'd like -- it's a funny question for me to answer 'cause I don't know how something would get to the market unless somebody had 'I got an idea, let's try this,' and I can't imagine anybody would bring something to the market with just 'Hey, I got an idea. Fred said let's try this. Let's put it in 50 people and see what works.' That doesn't make sense

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to me.
You're going to do some kind of like cadaver testing, animal testing, people testing, toxicology testing.
Q. But before you start selling it across this country, it's important that there be some clinical studies, some clinical data to support the product, correct?
A. I would like some scientific data to back it up. Clinical is a -- again, everything starts out, the best cure of any disease starts out with a very index patient using it for the first time, and it has to have some data to back up the rationale why we're going to use it.
Now, it might be classified as experimental there, but the patient's going to understand that it's experimental and is willing to take those risks.
Q. Exactly, but they --
A. There always has to be one patient who does something for the first time.

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Q. Of course. But that patient should be told that this is an experimental, you're the first patient, you're the fifth patient, it's not released to the general public yet, correct?
A. I think that's a fair statement, yes.
And you like to see some basic science data, animal studies, cadaver studies that back up what you do, whatever may be appropriate.
Q. Have you ever conducted any bench or laboratory research yourself on polypropylene mesh?
A. I have not.
Q. Have you ever tested different mesh material for the treatment of stress urinary incontinence?
MS. KABBASH: Objection to form.
A. I haven't done any formal testing. I've just used the different products and felt that some of them worked better for me.

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Q. What other products have you used other than the TVT family of products for the treatment of stress urinary incontinence?
A. I used the IFS tunneler device for a short period, and I used some synthetic slings and autologous fascia for pubovaginal slings early in my career as a resident to treat stress incontinence.
Q. Did you ever use a ProteGen sling?
A. No, thank goodness.
Q. Why is that? Why thank goodness?
A. That didn't end well for Boston Scientific.
Q. Do you know what the similarities and differences are between the ProteGen sling and the TVT slings?
A. Well, the ProteGen sling was a polyester weave with bovine collagen, and it also had bone anchors.
Just a lot of bad things there. Lot of bad potential complications with

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all of those things.
Q. You mentioned the tunneler device.
Did you have good experience with the tunneler device?
A. I did, but I felt uneasy with the mesh.
Q. You know that's not on the market anymore?
A. I know that. Actually, but I'm not as familiar with the IVF tunneler.
Q. Do you know why it was pulled?
A. No, I do not know.
Q. Did you ever use Covidien mesh?
A. I don't -- I wasn't aware that Covidien made a TVT. I think they make a sacrocolpopexy mesh which I believe I've used.
Q. What about Coloplast, do you use Coloplast slings?
A. I've used Coloplast now for my anterior and posterior vaginal mesh repairs, and it's my predominant Y-mesh for sacrocolpopexies.

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Q. Not for slings?
A. I haven't used Coloplast for slings, no.
Q. Any other manufacturers -- have you used any other manufacturers' products, mesh products, for the treatment of stress urinary incontinence other than Johnson & Johnson?
A. I've used the Caldera slings a few times.
Q. The Desara?
A. A Caldera I think is the name. It's the preset ones that -- it's put out by a company that basically mimics every sling that's on the market. So the advantage is a hospital can buy the complete set and it sort of mimics the Monarch, it mimics all the TVT products. They have a mimic for everything.
Q. Have you used the AMS products for SUI?
A. No, I don't think I have. If I did, it was just once or twice. I don't really recall. And if I did, it was

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probably in a cadaver lab setting somewhere. I really don't have any experience with AMS products.
Q. And Boston Scientific slings, same thing?
A. I did not use their slings. I used their Uphold for anterior and apical support.
Q. In those times where you removed mesh from women, TVT, Prolene mesh, did you request any particular analysis of the explanted mesh?
A. No.
Q. Did you personally review the pathology reports for those?
A. I'm sure that I did, and I'm sure that I probably sent it to pathology.
Q. Did you in that request a SEM analysis?
A. No.
Q. Did you request any particular analysis of those explanted meshes?
A. No, I did not.
Q. I take it you're not a

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pathologist?
A. No.
Q. And don't hold yourself out to be an expert on pathology?
A. No.
Q. Same with you're not an epidemiologist?
A. No, I'm not an epidemiologist.
Q. You're not a biomedical engineer?
A. Not a bit.
Q. And you've never done a comparison study of different mesh designs?
A. No, I have not.
Q. And you don't hold yourself out to be an expert in medical device design?
MS. KABBASH: Objection to form.
A. Not in the bench work of design, but I think I have a handle on what seems to work best for me and for other physicians in the O.R. just based on experience.
Q. But with regard to comparison of

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different designs, you don't have an expertise on that?
A. Beyond my own surgical experience, no.
Q. And you agree that would be anecdotal experience, correct?
MS. KABBASH: Objection.
BY MR. AYLSTOCK:
Q. I mean, I guess you haven't done a study on SUI. We've established that.
A. No, but the problem I have with anecdotal would mean that there's a total absence of any ergonomic literature suggesting that one handle might be better than another, and I'm not sure I could say that. So I'd say that my migration to certain products over my career probably involves as much how I can handle the device as what data may be out there supporting a superior design or ergonomics that agrees with what I'm feeling.
Q. So it's based upon your clinical experience in treating particular patients, correct?

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MS. KABBASH: Objection.
A. Supplemented with what I may be exposed to at the time regarding design advantages, et cetera.
Q. In your opinion, should a medical device company inform physicians about potential complications associated with its medical device?
A. Yes.
Q. And would you agree with me that one of the ways to do that is through the IFU for the medical device?
A. Yes.
Q. If you go to page 5 of your report. There's some information about your payment at the time of a preceptor.
Do you see that?
A. Yes.
Q. And you list, you state that you believe that Ethicon reimbursed you about $50,000 for those -- for that time; is that correct?
A. Yes.
MS. KABBASH: I apologize. What

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page are we on?
MR. AYLSTOCK: Page 5.
MS. KABBASH: Thank you.
BY MR. AYLSTOCK:
Q. Have you confirmed that, or is that just your best estimate?
A. That is -- I actually thought that number was less, but apparently I guess working for -- as a proctor or preceptor for many years ago, it did total that amount. That number was actually based on records from Ethicon.
Q. Did you look at those records?
A. No. But I can recall that standard rates for teaching somebody for half-day or a full day were about either $500 for a half-day and a thousand for a full day, and if I acted as a preceptor for a cadaver course, I think there was a higher fee for that. Those were pretty standard rates.
Q. Did they pay for your travel to these courses?
A. They probably would if I asked

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them, but I kind of just paid for my own travel.
Q. Did you receive any honoraria from them?
A. I'm probably misunderstanding the question because I thought that's what that was. That five hundred or a thousand, does that not qualify as an honoraria? I don't know. I got paid.
Q. You got paid for it, okay.
And I take it you've also got paid by Wyeth and GlaxoSmithKline and all of those other companies for your work for them, correct?
A. I got flat fees for giving talks. It was pretty much for the medical aspect of that consulting. It wasn't any -- with the exception of Covidien, it wasn't any involved with the company, per se. It was just flat fee. I was on their speaker panels, give talks.
Q. And you're still on various speaker panels and so forth, correct?
A. I don't think so. I think they

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outlawed those. At least my hospital did. You can't be on a speaker panel as of about four years ago.
Q. You're still being paid for doing things for medical device and pharmaceutical companies, correct?
A. That is correct.
Q. In addition to what you're doing in this case for Ethicon, correct?
A. Correct.
Q. You mentioned some things you reviewed, and that includes some procedural videos.
Do you see that?
A. You're down at the bottom of that page?
Q. Right in the middle "Materials Reviewed."
A. Yes.
Q. What procedural videos did you review?
A. I had a TVT -- I had several TVT videos -- "video" is a bad term. I'm probably dating myself. Disks. They

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weren't videos, they were disks.
Q. Okay.
A. That I used at the time. I haven't looked at them in a long time, but a lot of the material I used in terms of teaching, as well as educating myself, involved some videos.
Q. Where are those disks now? At your office?
A. I gave them away to residents.
Q. Were any provided to you by counsel in preparation for this report?
A. No.
Q. What about the surgeon's resource monograph, when is the last time you looked at that?
A. Recently. They showed me that and I recognized that. I recall that being my individual bible for doing a TVT when it first came out. I relied on that a lot.
Q. I'll skip over Secur because we're not talking about that today.
Now, when you are consenting a

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patient to do a TVT surgery or one of those family of products, would you agree with me that it's a joint decision as to whether or not that product should be implanted in that particular patient?
A. Yes.
Q. In other words, you're not going to implant it in a patient if the patient doesn't want it, correct?
A. That is very correct.
Q. And you as a conscientious doctor, you're going to make sure the patient understands the risks and potential benefits of the surgery, correct?
A. Yes.
Q. And then leave it to the patient to decide whether or not to go forward with the surgery, correct?
A. Correct.
Q. With regard to the bottom of page 10, you talk about in the presence of other abdominal surgery, stress urinary incontinence may be treated with a Burch

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procedure.
Do you see that at the bottom of page 10?
A. Yes.
Q. You would agree with me that performing a Burch procedure today is not below the standard of care for a physician, correct?
A. No, but I think that it's become so uncommon that the only time I've seen it performed in the last 10 to 12 years is in conjunction with an ongoing intraabdominal operation. I really don't see people doing Burch procedures as first line therapy for surgery for stress incontinence.
Q. Okay. But you wouldn't consider a Burch procedure below the standard of care, correct?
A. I think it's within the standard of care, but it's a little bit unusual. I mean, there are -- I actually had a urogynecology fellow who I was familiar with when she was a resident who told me

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when she graduated her urogynecology fellowship and she never saw a Burch.
So I think that it's probably not below the standard of care, but it would be unusual, extremely unusual for someone to be offering multiple Burch procedures for stress incontinence in lieu of midurethral slings.
Q. Go to page 11, if you would.
You're talking about the development of the TVT Retropubic here, and you cite to Professor Ulmsten and Petros, correct?
A. Correct.
What page are you on?
Q. Page 11.
A. I know it's in my report, but I don't see it on page 11.
MS. KABBASH: Let's make sure we're in the same place.
Let's use the numbered exhibit. Let's use Exhibit 6 to make sure you guys are in the same place.
He brought a copy of his report

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that he printed out. The pagination is a little bit different.
MR. AYLSTOCK: Okay. I would like a copy of what he brought as well. So why don't we mark that as Exhibit 10 just so we have it.
(Exhibit Wagner 10, Expert Report of John R. Wagner, M.D. regarding Gynecare TVT Products, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. So, page 11 you talk about Professor Ulmsten, correct, and his development of the TVT?
A. Yes.
Q. Do you know how the product he developed is different from the TVT Retropubic sold in the United States?
A. How the product he developed is different?
Q. Is it your understanding that he used the exact same product that's in this box of the TVT Retropubic that I brought?

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A. He used, actually it's my understanding that he used multiple different meshes before deciding to settle on the polypropylene mesh. I'm not aware that the device varied among those initial trials, but I do know that he tried different meshes.
Q. Okay. With regard to the studies that you relied on and are relied upon by Ethicon resulting from Dr. Ulmsten's work that then got continued by Dr. Nilsson after Dr. Ulmsten's death, do you know whether or not those devices in those studies are identical or in any way different from the TVT device that I brought with me here today, the retropubic device?
A. It's my understanding that the original TVT devices are those devices.
Q. And by "those" you mean the one I brought with me in the box, the TVT Retropubic device?
A. Correct.
Q. So it's your understanding that

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there's no differences whatsoever?
MS. KABBASH: Objection to form. You can answer.
A. I'm not aware of any substantial difference. I don't know if maybe the handle's different in one or another or could it screw in with different, you know, different -- I mean, it could be a small difference, but I think the tape is the same tape and I think the device is generally the same device. It's been my understanding they're pretty much interchangeable.
Q. But as we sit here today, you can't explain what the differences are, if any?
A. That's correct.
Q. In fact, you don't even know whether there are differences?
A. That is correct.
Q. You would agree with me that the other manufacturers' mesh, AMS, Boston Scientific, Caldera, Coloplast and so forth that we talked about, are different

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formulations of mesh than the Prolene mesh in the TVT family of products, correct?
MS. KABBASH: Objection; beyond the scope.
Go ahead.
A. I'm aware, yes.
Q. You mentioned here about TVT has earned the reputation as the gold standard of the treatment of SUI.
How do you define "gold standard"?
A. It's sort of like minimally invasive. It's a relative term, but I think if you look in the literature, particularly systemic reviews of the literature, the primary midurethral sling used worldwide is the TVT. The vast majority of literature available concerns the TVT, and the longest follow-up we have of any device with the TVT.
Q. So I'm clear, when you say "TVT" in your preceding answer, you're talking about the TVT Retropubic device, correct?
A. That's the one with the longest

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track record.
Q. Okay. And the TVT Retropubic is a midurethral sling, correct?
A. Correct.
Q. Are the other TVT products also midurethral slings, or are there differences?
A. Yes, they all are.
Q. Do you know whether Dr. Ulmsten's, the type of product Dr. Ulmsten used that then was followed up by Dr. Nilsson was a TVT laser-cut or a TVT mechanical-cut?
A. I always made the assumption it was mechanical-cut. I thought a laser-cut came along later, but I could be wrong on that.
Q. You don't know as you sit here today?
A. I don't know with a hundred percent certainty, no.
Q. And with regard to the studies you referenced that support the TVT Retropubic device, do you know how many of

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them involved TVT mechanical-cut versus TVT laser-cut?
A. No.
Q. Are you familiar with -- well, I guess you've never actually implanted a TVT laser-cut -- TVT Retropubic laser-cut, to your knowledge, correct?
MS. KABBASH: Objection to form.
A. I actually don't know that. I consider those slings interchangeable. I know I've implanted the mechanical-cut, but as far as I'm aware, I could have easily implanted a laser-cut mesh. It would have been the same to me.
Q. You wouldn't know the difference if you held it?
A. I mean, if I really carefully pulled on it and tugged on it and tried to wreck it, I'd see the difference, but I'm not trying to pull and tug it and wreck it before I put it in. So to me they're interchangeable.
Q. So you don't know the biomechanical properties of each and

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whether they're the same or different?
MS. KABBASH: Objection to form.
A. To my mind, they're clinically the same.
Q. Do you know whether or not the TVT laser-cut is stiffer mesh than the TVT mechanical-cut?
A. Again, I come back to clinically to me, it makes no difference to me whether it's laser-cut or mechanical-cut.
Q. You say clinically, but you don't know as we sit here today whether you've actually ever implanted a TVT laser-cut retropubic, correct?
MS. KABBASH: Objection to form.
A. That is true. But it's not a characteristic that I would ever insist upon, and so I could have implanted multiple laser-cuts. I'd actually have to check the requisition office in our hospital and in my other hospital to see what they ordered. But I do know that I have used the mechanical-cut mesh.
Q. And the reason you don't know

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the difference is because Ethicon never explained to you as a doctor implanting 800 TVT Retropubic devices what the reasonable differences are between the laser-cut mesh and the mechanical-cut mesh in the TVT-R, correct?
MS. KABBASH: Objection to form.
A. Actually, that's not exactly true because I had a long discussions with my rep regarding laser-cut with the TVT Secur. So I was actually familiar with the laser-cut and what it looked like. And so, and I also know that if you put excessive force on the mechanical-cut, it looks different than if you put excessive force on the laser-cut. I just don't think that it has any clinical relevance to me as the implanting surgeon on a standard tension-free tape. I'm not putting -- if I'm putting excessive force on that tape and deforming it, then I'm doing it wrong. It's not the tape, it's the doctor.
Q. Okay. So you've observed in

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your experience with the TVT devices that when you pull on the mechanical-cut mesh, it has more deformation of the pores than if you pull on mechanical-cut mesh, fair?

MS. KABBASH: Bryan, in fairness, I think you misstated a word. You might want to --

MR. AYLSTOCK: I'll try again. Thank you.

MS. KABBASH: You're welcome.

BY MR. AYLSTOCK:

Q. In your prior answer, you had indicated that when you're putting force on the mechanical-cut mesh to a certain extent, it behaves differently than the same amount of force on a laser-cut mesh, correct?

A. Yes.

Q. And can you describe the differences, please, as you've observed in your clinical practice?

A. What I've seen actually is two observations. One is if I'm teaching somebody and they put way too much tension

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on the mesh, it tends to rope or band maybe and not lie flat. And in that setting, you can also get some irregularity of the edges. And that's clearly a tape that's been inappropriately placed.

The other time that I've noticed the properties of laser-cut versus mechanical-cut is when I'm removing the mesh that I don't like how it's been placed. I found that if I pulled out a laser-cut TVT Secur, that it would maintain its shape a lot better than if I was tugging on mechanical-cut mesh in the process of removing it. I could never really use that mesh again. I'd have to get a new product out of the box because the process of extra tension had deformed it.

But it wasn't -- basically from a properly placed mesh to me, it makes no difference to me whether it's mechanical-cut or laser-cut.

Q. Did you see when that force was

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applied to the mechanical-cut evidence of fraying of the mesh? Could you see that? Could you see the fraying of the mesh if the mechanical-cut was pulled?

A. You could see irregularity in the mesh. I guess you would call that fraying. I just always thought of it as an irregularity. The edges were jagged if you applied too much tension to it.

Q. Like a barbed wire effect?

MS. KABBASH: Objection.

A. It would have -- it would have -- I would describe not barbed wire. As more like looking at a mountain range, where you have the peaks and valleys of the mountains.

Q. A jagged edge?

A. Yeah, like that.

Q. Now, did you see evidence of particle loss, or particles?

A. Occasionally I would see -- my clamp that I'm using to tug on the mesh for whatever reason could rip the mesh, tear the mesh, there might be a little

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particle here or there.

Q. You mentioned the need to make sure the mesh was lying flat under the urethra?

A. And without tension.

Q. Why is it important that that mesh be laid flat?

A. I think there's two answers to that question. The first is that it provides a slightly broader base of support rather than a very narrow base of support.

But the other answer to that question, the reason it's important is because if it's not lying like that, somebody's over-tensioning it.

Q. Okay. Now, you agree that when implanting a TVT device, really any of the TVT family of products, but certainly the TVT Retropubic, that it's a blind passage, correct?

A. Yes, it is.

Q. And you as a physician can't visualize that mesh lying under the

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urethra, correct?
MS. KABBASH: Objection.
A. Well, yes, you can because you made an incision there. So once you placed it, you can see the mesh underlying the urethra.
Q. But the passages of the polypropylene that are going through the rest of her body via the tunnels created by trocars, you can't visualize that mesh, correct?
A. No, you can only see the portion of the mesh that's visible with your suburethral dissection and obviously the portion of the mesh that's sticking out of the skin incision.
Q. You mentioned earlier the words "roping" and "banding."
Why is it important that the TVT mesh not rope or band inside of a patient's body?
A. I think there's two answers to that question. The first answer is the obvious. If you see that, it's probably

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over-tensioned and it probably is going to cause significant obstructive problems in that patient postoperatively and it needs to be loosened.
Q. Can I stop you there?
Why would it cause significant postoperative patients if it's roped or band?
A. Because it suggests it's too lightly placed. It's not tension free.
Q. Okay. And in that context, would the problems that it could cause include urinary obstruction?
A. Yes.
Q. Could lead to excessive scar tissue around that banded mesh?
A. No, I think it's just urinary obstruction. And I also think to, to finish my answer, there's a second point that I think is a problem.
If it bands, then the surface area applied to the urethra is much smaller and it's much easier potentially for that mesh to cut into tissue or

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potentially erode into the urethra. You know, a small band could act like a sharp suture or like a -- like a cheese cutter, it can just kind of cut through, and you wouldn't want to do that.
So, I think the other problem is not that it's just too tight, but if it bands like that, it potentially, theoretically in my mind, could increase risk for erosion.
Q. Have you seen any studies that have looked at whether one physician can feel the palpable banding in patients and to what -- at what rate following implantation of the TVT family of products device?
A. I think banding is something you'd have to see or feel almost intraoperatively. Once you get within a few weeks of the surgery, any band is potentially normal scar tissue that's filling in there, not dissimilar to somebody who, let's say, has an obstetrical laceration and we do a vaginal

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repair and at the six week visit we feel a dense band across the episiotomy or laceration site where it healed that normally. So within four to six weeks, anything you felt there is more likely to be scar tissue and not the mesh itself. I think if you're going to feel band, it would have to be right away.
So, I don't think I've seen any literature that you can reliably count on that says you can diagnose a band by a palpation. I think more often than not, that's probably scar tissue.
Q. Well, have you ever seen any studies that looked at banding and whether you can palpate banding following implantation of the TVT device?
A. I don't recall seeing any studies like that.
MS. KABBASH: I think we're coming up on three hours very soon.
MR. AYLSTOCK: Why don't we go off the record then and add it up.
(Recess taken at 12:14 p.m. to

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12:22 p.m.)
EXAMINATION BY
MS. KABBASH:
Q. Doctor, I have some follow-up questions for you.
Plaintiff's counsel asked you some questions about a case of mesh exposure and he specifically asked you if you had reported that case where you removed some mesh to Ethicon or the FDA.
Do you recall being asked that?
A. Yes.
Q. And I believe you answered "no."
Is that right?
A. Correct.
Q. Why did you not choose to report that particular case to Ethicon or the FDA?
A. I've never reported any case of mesh erosion to any company at all.
Q. And why is that?
A. We -- we -- that's basically sort of a normal expected potential complication of any mesh repair. If I

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tell a patient or when I counsel a patient regarding suburethral slings or any vaginal mesh repair, I'm going to counsel them regarding the risk of mesh complications, is how I would put it, and that would include erosion or, more commonly, extrusions. And extrusions is usually what we see the more recent onset, and those are either treated in the office or in an outpatient surgery setting.
So what I tell patients is basically this can happen. It might require something that we have to manage here in the office. At least half the time or better we can just take care of it in the office, and it might require a return to the operating room for a small procedure just to remove that little piece of mesh and to put a couple stitches over the repair. I really -- when I talk to patients about it, I don't describe it as a major issue.
Q. Is mesh exposure a known potential risk of using a midurethral

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sling?
A. Yes.
Q. Is it reported in the medical literature?
A. Yes.
Q. Is it reflected and warned about in the TVT instructions for use?
A. Yes.
Q. If you could pull out Exhibit 8, which is the abstract or the summary of the vaginal repair of symptomatic pelvic organ prolapse poster that you authored.
A. Yes.
Q. Plaintiff's counsel asked you several questions about this abstract before, this poster I should say, and in particular with respect to the type of mesh that was used in the study.
Do you recall that?
A. I do.
Q. At the time of the study, were you using the Gynemesh PS polypropylene mesh put out by Ethicon?
A. Yes.

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Q. Is that the type of mesh that was used in this study?
A. Yes.
Q. To the extent that you earlier indicated to Mr. Aylstock that you were using a product called Prolene mesh, is that something that you need to correct to Gynemesh PS?
A. Yes. I actually thought those two types were interchangeable. So you need to correct that. I was using the branded name is Gynecare PS that I used.
Q. Was it Gynecare Gynemesh PS?
A. I think it was Gynemesh PS. Honestly, it's been a long time ago 'cause I stopped using it ten years ago. I think it was Gynemesh PS.
Q. Do you remember if it was the same mesh that was later used in the Prolift kit?
A. Yes, I do remember that. It was the same mesh that was used in the Prolift kit.
Q. But it came in a flat sheet?

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A. Came in a flat sheet.
MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. Earlier plaintiff's counsel was asking you about particular articles going through your reliance list and you made a statement something to the effect that "I don't consider any particular article to be authoritative."
Do you remember saying that?
A. Yes.
Q. What did you mean when you said that?
A. That there's no one forever unimpeachable authority really in anything we do in medicine. There's no book chapter. There's no article. There's no opinion piece. There's no authority in medicine that is unimpeachable.
Q. Your expert report on the TVT products cites a lot of medical literature, correct?
A. It does.

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MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. In stating your opinions or formulating your opinions on TVT Retropubic, did you rely on any one article to the exclusion of others?
A. No.
Q. Were you relying on the body of medical literature that has evolved on TVT slings over time?
A. Yes.
Q. You were asked several questions about a TVT IFU that was marked as Exhibit 9. Can you pull that out? And I think if you turn to page 5 of the IFU that's where are listed several potential adverse reactions that counsel was asking you about.
Is that right?
A. Yes.
Q. And counsel asked you a series of questions about whether certain risks could be caused by TVT and if they could

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happen in the absence of doctor error.
Do you recall that line of questioning?
A. Yes.
Q. One of the risks that you were asked about was acute or chronic pain.
Do you recall that?
A. Yes.
Q. Is acute or chronic pain a potential risk of any pelvic surgery?
A. Yes.
Q. Is it a potential risk of any surgery to treat SUI irrespective of the use of mesh?
A. Yes.
Q. You were also asked about the potential risk of pain with intercourse that may not resolve.
Do you recall that?
A. I do.
Q. Is that a potential risk of any pelvic surgery?
A. Yes.
Q. Is it a potential risk of any

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surgery to treat SUI irrespective of the use of mesh?
A. Yes.
Q. In other words, it's a potential risk of SUI surgery that does not use mesh also?
MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. Correct?
A. Correct.
Q. You were also asked about the potential risk of voiding dysfunction.
Is voiding dysfunction a risk of any pelvic surgery?
A. It's a risk of any pelvic surgery, particularly those that are involved with treating incontinence.
Q. Okay. Is voiding dysfunction a potential risk of any surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were also asked about neuromuscular problems or pain.

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Do you recall that?
A. Yes.
Q. Is neuromuscular problems or pain a potential risk of any surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were asked about bleeding including hemorrhage or hematoma.
Do you recall that?
A. Yes.
Q. Is that a potential risk of any surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were asked about the potential risk that repeat surgeries may be required.
Do you recall that?
A. I do.
Q. Is that a potential risk of surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were also asked about the

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potential risks of seroma, urge incontinence, frequency and atypical vaginal discharge.
Do you recall that?
A. Yes.
Q. Are all those potential risks of surgery to treat SUI that do not involve mesh?
MR. AYLSTOCK: Objection to form.
A. Yes.
Q. You were asked earlier today when was the last TVT Retropubic device that you performed.
Do you recall that?
A. Yes.
Q. You currently use the TVT-Exact; is that right?
A. Correct.
MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. Is the TVT-Exact similar to the TVT original Retropubic?

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MR. AYLSTOCK: Objection to form.
A. Yes.
Q. You previously described some of the things that you liked about the TVT-Exact, but is the --
MS. KABBASH: Strike that.
Q. Is the TVT-Exact a retropubic approach to placement of a midurethral sling?
A. Yes.
Q. Are the trocars, though they may be a bit narrower, are they the same shape as the trocars for the TVT Retropubic sling?
MR. AYLSTOCK: Objection to form.
A. Yes.
Q. Is the knit of the mesh in the TVT-Exact the same knit as in the TVT Retropubic sling?
A. Yes.
Q. You were asked earlier today about whether you are a biomaterials

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engineer.
Do you recall that?
A. Yes.
Q. Have you studied, both in your career and in preparing your expert report, how the Prolene mesh in TVT has performed after being implanted in women?
MR. AYLSTOCK: Objection to form.
A. I've watched how it's performed not only in my patients, but also how it's performed through the vast years of medical literature and studies have been done on it.
Q. And is a lot of the medical literature that you have studied in that regard cited in your expert report?
MR. AYLSTOCK: Objection to form.
A. Yes.
Q. How important is the clinical literature, the medical literature as a basis of your opinions about the safety of the use of the TVT implant?

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MR. AYLSTOCK: Objection to form.
A. How the mesh works in people and how successful it is long-term and the side effects long-term we measure clinically in our reports to me is the best evidence we have for safety and efficacy. We want to know how it actually works in people and we want to know as much as we can about that.
Q. And is that why you've cited that medical literature in your report?
A. Yeah, the medical literature I have in my report includes a tremendous amount of clinical data on real life people having real life mesh placed to treat incontinence over many years.
Q. If you turn to your report's opinion number 2, which is towards the end on page 52.
You have that?
A. I think I do have it.
Q. Opinion 2 says: "The benefits of these products far outweigh their risks

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in properly selected surgical candidates based on their performance in thousands of women. As reflected in the medical literature as well as my experience, they are not defectively designed."
Do you see that?
A. I do.
Q. With respect to the TVT Retropubic, does that continue to be your opinion?
A. Yes.
Q. And do you hold that opinion to a reasonable degree of medical certainty?
A. Yes.
Q. Is your opinion that the mesh in TVT is not defectively designed based on your review of the medical literature, as well as your experience?
A. Yes, as well as my interaction with colleagues and opinions of surgeons that I respect. It's the entire body of evidence in our urogynecologic community.
Q. If you turn to opinion number 8, which is on the last page of your report.

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It says: "The possible risks of the TVT family of products are appropriately described in their instructions for use, the patient brochures for the TVT family of products, and in Ethicon's professional education materials."
Do you see that?
A. Yes.
Q. What are the sources of information that --
MS. KABBASH: Well, first of all, strike that.
Q. Do you continue to hold that opinion today?
A. Yes.
Q. Do you hold that opinion to a reasonable degree of medical certainty?
A. Yes.
Q. And on what sources of information do you base that opinion?
A. I base it on pretty much the same thing. I base it on my training, my experience, my interaction teaching residents and fellows, interacting with

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other urogynecologists, the medical literature, the extent of the medical literature, the quality of the data, and the quality of data that's presented at national meetings and -- that I've attended and read summaries of.
Q. And have you assessed the warnings of adverse reactions section of the TVT IFU in relation to all those sources of information that you just mentioned right now?
A. Yes, I have.
Q. Do you recall if you used the TVT Retropubic, the original, up until the time that TVT-Exact came out on the market?
In other words, I know that you testified that you used TVT Secur, but were there some patients in which you would use TVT Retropubic up until the time that Exact came out on the market?
A. Typically, if they had failed a mini sling, such as the Secur or there was an Adjust, which is another mini sling

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that I used occasionally, or if they were referred to me and had failed a transobturator sling, I might lean towards a Retropubic TVT, but -- but those would be the instances, but even in some of those circumstances, I might still put a Secur in.

Q. If TVT-Exact came out on the market in 2010, I'll ask you to assume that.

A. Okay.

Q. If that's the case, would you have continued to use TVT Retropubic in certain patients, at least through that period of time, 2010?

MR. AYLSTOCK: Objection to form.

A. If the TVT-Exact were not on the market, I would be using the TVT Retropubic every time I placed an Exact in today's world.

Q. Let me re-ask my question. I think we -- you might have answered a different question than the one I asked you.

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Assuming that the Exact came out in 2010, would you have used the TVT Retropubic, or did you use the TVT Retropubic up until the time the TVT-Exact came out in the patients in which you wanted to use a full-length midurethral sling?

A. Yes, I did.

Q. You were asked some questions before about your use of laser-cut mesh.

Do you recall that?

A. Can I go back to that last question and just make sure that I understood what your question was?

Q. Okay.

A. Which is is that -- and maybe I can phrase it a different way so that I'm clear on this. When the TVT-Exact came out, I did switch over to that relatively quickly because I felt, as I said before, just more comfortable with it.

Is that the question that you were asking there?

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Q. And up until the time that the TVT-Exact came out, you would have been using the TVT Retropubic in patients in whom you wanted to do a full-length retropubic approach sling?

A. Yes, exactly.

Q. You were asked some questions about your use of laser-cut mesh.

You use TVT Secur, correct?

A. Yes.

Q. For several years?

MR. AYLSTOCK: Objection to form.

BY MS. KABBASH:

Q. Is that right?

A. It is correct, yes.

Q. And TVT Secur employed a laser-cut mesh, right?

MR. AYLSTOCK: Objection to form.

A. Yes, it did.

Q. And you also have used TVT-Exact?

MR. AYLSTOCK: Objection to

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form.

A. I have.

Q. And were you aware that that also employs a laser-cut mesh?

MR. AYLSTOCK: Objection to form.

A. I wasn't specifically aware of that. But as I think about it, it does look laser-cut to me.

Q. And you also currently use TVT Abbrevo; is that right?

A. I do.

MR. AYLSTOCK: Objection to form.

BY MS. KABBASH:

Q. And you've used Abbrevo for the past six or seven years?

MR. AYLSTOCK: Objection to form.

BY MS. KABBASH:

Q. No, I'm sorry. You've used Abbrevo for the past five years?

MR. AYLSTOCK: Objection to form.

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A. Four or five years, yes.
Q. Okay. Have you ever seen evidence that the mesh in TVT would rope or band in the absence of being overly tensioned by the surgeon?
MR. AYLSTOCK: Objection to form.
A. No.
Q. Mr. Aylstock brought a sample of the TVT device today, and the mesh implant has a sheathe on it, does it not?
A. Yes, it does.
Q. A plastic see-through sheathe?
A. Yes.
Q. What is the purpose of that sheathe?
A. To aid in placement of the sling by minimizing any local trauma that the tape might cause as it's being put in place, and also to minimize any risk of infection.
Q. When you're tensioning the TVT sling, is it your practice to use any kind of instrument in the tensioning process?

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A. Typically I use a uterine dilator, a number 8 dilator, number 10 dilator, somewhere in that range, but a Hegar dilator to place between the tape and the urethra while I'm tensioning it -- while I'm removing the plastic covers.
Q. And why do you do that?
A. To assure that it's not overly tensioned.
Q. And is that a well-known technique to use some sort of instrument to maximize the proper placement or proper tensioning of the device?
MR. AYLSTOCK: Objection to form.
A. Yeah, people use various instruments just to assure the normal tension -- the proper tension of the sling.
MS. KABBASH: I don't have any more questions.
How much more time does Bryan have?
THE COURT REPORTER: If it's

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three hours, it's up.
THE WITNESS: He's done.
MS. KABBASH: Go ahead and have a minute because I believe in professional courtesy.
I've been held to a very tough standard by some of your colleagues on this.
MR. AYLSTOCK: No, I understand.
FURTHER EXAMINATION BY MR. AYLSTOCK:
Q. Your opinion 8 in your report about the IFU being properly describing the risks, is that -- are you referring to Exhibit 9 with regard to that report with regard to the risks described?
A. Yes.
Q. And you changed your testimony, or I guess you were asked questions about the type of mesh in your study.
Do you recall those questions?
A. Yes.
Q. And I take it you discussed the type of mesh in that study during break

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with counsel, correct?
A. I did 'cause she asked me what it looked like, what was the name of it, and I was --
Q. She was the one who suggested to you that it was Prolene Gynemesh PS?
MS. KABBASH: I'm going to object to this line of questioning, but you can go ahead and answer.
Q. Not Prolene, correct?
A. Actually, I remember the Gynemesh PS as being the mesh. That wasn't the issue. My mistake was thinking that that was the same mesh as the TVT. In fact, that mesh is the same as what's in the Prolift in terms of its dime -- pore diameter and things like that.
So, actually it was my error. It wasn't I didn't remember what I put in. It's that I was under the impression that that mesh pore size more reflected the TVT pore size, not the -- but instead it actually reflected the Prolift pore size.
Q. Okay. So you didn't know that

at the time we came in here?
MS. KABBASH: Objection.
A. I knew the mesh I put in. I didn't know the pore size of the -- I was incorrect in stating -- in thinking and alluding to the fact that the Gynemesh PS had the same pore size as the TVT. I was under that impression, and counsel corrected me, that it was actually the same as the Prolift pore size.
MR. AYLSTOCK: Thank you.
Thank you, Maha. I appreciate that.
(Deposition adjourned at 12:45 p.m.)

ACKNOWLEDGMENT

STATE OF)
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COUNTY OF)

I, JOHN WAGNER, M.D., hereby certify that I have read the transcript of my testimony taken under oath in my deposition of March 13, 2017; that the transcript is a true and complete record of my testimony, and that the answers on the record as given by me are true and correct.

_____
JOHN WAGNER, M.D.

Signed and subscribed to before me this _____ day of _____, 2017.

_____
Notary Public, State of

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CERTIFICATE
STATE OF NEW YORK
COUNTY OF NEW YORK

I, Marie Foley, RMR, CRR, a Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:
THAT JOHN WAGNER, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.
I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.
IN WITNESS WHEREOF, I have hereunto set my hand this 17th day of March, 2017.

_____
MARIE FOLEY, RMR, CRR